HOME Program, they would follow the procedures outlined above.

For any consortium request for the HOME Program received by August 1 of this year and by March 31 of subsequent years, the HUD Field Office will review the documentation to determine whether the consortium is made up of geographically contiguous units of general local government and whether the consortium has sufficient legal authority and administrative capability to carry out the purposes of the HOME Program on behalf of its member jurisdictions. (Requests received after August 1, 1991 for an allocation of HOME funds in FY 1992 will not be considered for funding until FY 1993.)

Legal Authority

Regional or Field Office Counsel should review each consortium's request to determine if the consortium has sufficient legal authority to carry out the HOME Program. Further guidance to HUD Regional and Field Office Counsel will be provided by the Office of the General Counsel.

Administrative Capacity

If the consortium includes a metropolitan city or an urban county as the lead entity, the consortium would be considered to have sufficient administrative capability unless it includes as its administrative capability to carry out the purposes of the HOME Program. If the consortium does not include a metropolitan city or an urban county, but the lead member or an existing public agency has relevant experience (e.g., successful experience in administering a CDBG or Rental Rehabilitation Program), the consortium could also be considered to have sufficient administrative capability to carry out the HOME Program. On the other hand, a newly created public agency established to administer the HOME Program for a consortium would not be viewed as having sufficient administrative capability unless it includes as its administrator(s) a person or persons with relevant experience in successfully administering programs similar to the HOME Program, such as the CDBG or Rental Rehabilitation Programs.

If the HUD Field Office is satisfied that the consortium meets the requirements for the HOME Program and has the relevant experience, legal authority and administrative capability to carry out the HOME Program, it will approve the consortium request.

The HUD Field Office is to submit to the Data Systems and Statistics Division, CPD, HUD Headquarters, with a copy to the Office of Urban Rehabilitation, CPD, by September 1, 1991 for FY 1992 consideration and by April 30 for each subsequent year, a list of each approved consortium indicating the members of the consortium and the locality that has been designated to act in a representative capacity for all member units of local government. HUD will make every effort to accommodate consortia requests received by August 1, 1991 for the FY 1992 HOME allocations. However, where consortia include areas that are not CDBG entitlements, it may be a problem to assemble data in time to allocate funds for FY 1992. If funds are available for allocation, the Department will not delay allocation of the funds to allow time to assemble data for CDBG non-entitlement members of consortia.

A consortium's status as a unit of general local government for purposes of the HOME Program continues for three Federal fiscal years.

Other Matters

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations in 24 CFR part 50 which implement section 102(2)(C) of the National Environmental Policy Act of 1969, 42 U.S.C. 4332. The Finding of No Significant Impact is available for public inspection during regular business hours in the Office of the General Counsel, Rules Docket Clerk, room 10276, 451 Seventh Street SW., Washington, DC 20410–0500.

Authority: Title II, sections 216 and 217, of the Cranston-Gonzalez National Affordable Housing Act (Pub. L. 101–625); section 7(d), Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: July 19, 1991.

Anna Kondratas,

Assistant Secretary for Community Planning and Development.

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federal register

Thursday
July 25, 1991

Part III

Department of Housing and Urban Development

Office of the Assistant Secretary for Community Planning and Development

NOFA for HUD-Administered State Rental Rehabilitation Programs; Notice

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Community Planning and Development

[Docket No. N-91-3284; FR-3089-N-01]

NOFA for HUD-Administered State Rental Rehabilitation Programs for Fiscal Year 1991 and Deadlines for Submission of Program Descriptions

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of funding availability for fiscal year 1991 and deadlines for submitting program descriptions for HUD-administered State rental rehabilitation programs.

DATES: Program Descriptions should be addressed to the CPD Division Director and must be submitted to the appropriate HUD Field Office by 4 p.m., local time, on or before August 26, 1991.

SUMMARY: This NOFA announces allocations of Rental Rehabilitation Program grant funds available by competition to units of local government in States which have chosen not to administer the Rental Rehabilitation Program in Fiscal Year 1991. It also announces the dates by which Program Descriptions must be submitted to HUD for these localities to be considered for grants, and it describes the application process and the selection criteria for these grants.

FOR FURTHER INFORMATION CONTACT: Mary Kolesar, Director, Rehabilitation Management Division, room 7162, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC, 20410-7000; telephone (202) 708-2470. Hearing- or Speech-impaired individuals may call HUD's TDD number (202) 755-2565. (These are not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act Statement

The information collection requirements for the Rental Rehabilitation Program have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (Pub. L. 96-511) and assigned the control number 2506-0080.

I. Purpose and Substantive Description

(a) Authority

The Rental Rehabilitation Program (RRP) is authorized by section 17 of the United States Housing Act of 1937 (42 U.S.C. 1437o), as amended, hereafter referred to as section 17. The program regulations are published at 24 CFR part 511. The program provides grant funds to States and units of general local government for the rehabilitation of privately owned real property to be used for primarily residential rental purposes. A statutorily based formula establishes the amount of grants available to most cities having a population of 50,000 or more, urban counties, consortia of units of general local government having a combined population of 50,000 or more, and to all States and the Commonwealth of Puerto Rico. However, a State may elect to have HUD administer its allocation for a particular Federal fiscal year. This NOFA announces the funds available by competition to units of general local government in all States which have elected to have HUD administer their RRP allocations for FY 1991.

Under 24 CFR 511.52, if a State elects not to administer its allocation for any fiscal year, the responsible HUD Field Office will make grants to units of general local government located within the State, for use in a local Rental Rehabilitation Program.

(b) Allocation Amounts

The following are the States that have chosen not to administer the RRP for FY 1991 and the amount of funds available by competition to units of general local government in each State:

State	Funds available
Arkansas	$342,000
California	1,689,000
Florida	572,000
Hawaii	36,000
Nevada	51,000
North Dakota	76,000
Oregon	279,000
Total	3,045,000

(c) Eligibility

Eligible applicants are units of general local government that do not receive formula allocations under 24 CFR 511.31(a), and that are located in States that chose not to administer the RRP (see preceding section (b)). Applicants which were eligible for a formula allocation under 24 CFR 511.31(b), but not 511.31(a), and which did not accept such allocations are also eligible to participate in a HUD-Administered Program. The units of general local government which were eligible for formula allocations under 24 CFR 511.31(b) are listed in appendix C to the NOFA for Formula Allocations for the Rental Rehabilitation Program for Fiscal Year 1991 and Deadlines for Submission of Program Descriptions, at 56 FR 21574, published on May 9, 1991. FY 1991 RRP funds under a HUD-Administered State Program may not be used in any portion of any otherwise eligible jurisdiction which is also an area eligible for assistance under title V of the Housing Act of 1949 (administered by the Farmers Home Administration (FmHA)). Further, units of general local government which are totally title V-eligible are not eligible to apply for FY 1991 RRP funds.

(d) Selection Criteria/Ranking Factors

Appendix A to this NOFA describes the selection criteria and ranking factors for Field Offices to use in choosing grantees from among those that submit Program Descriptions pursuant to § 511.20 which are determined to be otherwise satisfactory pursuant to § 511.21(b) of the regulations.

The selection system is designed to select among such otherwise approvable Program Descriptions as required by § 511.52 of the program regulations. The factors that will be used to rank the applications are (1) need, (2) past performance in housing and community development activities, (3) program administration, and (4) quality and impact of the proposed program. Appendix A sets out the weight and relative importance of the factors.

II. Application Process

The Program Description is the application for the Rental Rehabilitation Program.

To be considered for a grant in a HUD-Administered State Program, units of general local government must submit a Program Description to the appropriate HUD Field Office, as required by § 511.52 of the program regulations. For all HUD-Administered State programs for FY 1991, units of general local government wishing to participate in the program must submit a Program Description by August 26, 1991. The Program Description should be submitted to the Director of the Community Planning and Development (CPD) Division in the applicable HUD Field Office, not later than 4 p.m. local time on the stated date. Field Offices are being advised to stamp each program description with the actual date and time of receipt. The details on selection criteria and application processing, including how to apply and how selections will be made, are contained in Chapter 6 (HUD-Administered Programs) and appendix 6-1 (Review Process Statement for HUD-Administered Rental Rehabilitation Program for Small Cities) of the Rental

Rehabilitation Program Handbook (HB 7360.01). However, so that the selection criteria and factors for award are available to all eligible applicants, HUD is publishing portions of the Review Process Statement for HUD Administered Rental Rehabiliation Program for Small Cities as appendix A to this NOFA.

III. Checklist of Application Submission Requirements

The elements to be contained in the Program Description and the certifications to be submitted with the Program Description are stated in appendix A to this NOFA.

IV. Corrections to Deficient Applications

Applicants will only be permitted to correct those deficiencies determined to be technical, i.e., those that do not change the substance of the application, e.g., a missing certification, or missing signature. Applicants will be required to cure any such deficiency within 14 days from the date of HUD's written notice to the applicant of the problem(s). Deficiencies determined to be substantive may not be corrected. Such incurable deficiencies include those which affect the relative ranking of applications under the selection critieria.

V. Compliance with Section 102 of the Department of Housing and Urban Development Reform Act of 1989

On March 14, 1991, the Department published in the **Federal Register** a final rule to implement section 102 of the Department of Housing and Urban Development Reform Act of 1989 (24 CFR part 12, 56 FR 11032). Section 102 contains a number of provisions that are designed to ensure greater accountability and integrity in the provision of certain types of assistance administered by the Department.

Since HUD makes assistance under the HUD-Administered State Rental Rehabilitation available on a competitive basis, part 12 requires HUD to:

—Ensure that documentation and other information regarding each application submitted to the Department are sufficient to indicate the basis upon which assistance was provided or denied. HUD must make this material available for public inspection for a five-year period. (§ 12.14(b)) HUD will provide further guidance on how this material may be accessed in a later notice to be published in the **Federal Register**.

—A notice will be published in the **Federal Register** indicating the recipients of the assistance made available under this NOFA.

VI. Other Matters

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations in 24 CFR part 50 which implement section 102(2)(C) of the National Environmental Policy Act of 1969, 42 U.S.C. 4332. The Finding of No Significant Impact is available for public inspection during regular business hours in the Office of the General Counsel, Rules Docket Clerk, room 10276, 451 Seventh street SW., Washington, DC 20410–0500.

The General Counsel, as the Designated Official under section 6(a) of Executive Order 12612, Federalism, has determined that this NOFA does not have Federalism implications and, thus, is not subject to review under this Order. This NOFA does not alter the established roles of State and local governments in the administration of the Rental Rehabilitation Program.

The General Counsel, as the Designated Official under Executive Order 12606, The Family, has determined that this NOFA does not have potential significant impact on family formation, maintenance, and general well-being, and, thus, is not subject to review under the Order.

The Catalog of Federal Domestic Assistance program number is 14.230, Rental Housing Rehabilitation.

Authority: Section 17, United States Housing Act of 1937, 42 U.S.C. 1437o; Section 7(d), Department of Housing and Urban Development Act 42 U.S.C. 3535(d).

Dated July 19, 1991.

Anna Kondratas,

Assistant Secretary for Community Planning and Development.

Appendix A—Section I, Program Description for Localities Participating in a HUD-Administered State Rental Rehabilitation Program for Small Cities

Program Description requirements for localities participating through a State-wide competition are very similar to Program Description requirements for localities receiving direct allocations of Rental Rehabilitation Program funds by formula. Of the following requirements, the parts that are underlined are additional items that are needed for competitively evaluating the Program Descriptions pursuant to section 511.52(b). Otherwise, the requirements are the same as stated in section 511.20(b) and(c) of the program regulations, except for the addition of the certification regarding lobbying (See item 16.g of this section I).

HUD Field staff will be available to answer questions from potential applicants concerning their Program Descriptions. However, once the application has been submitted for evaluation, the applicant will not be given an opportunity to revise its Program Description except for technical corrections (those that do not change the substance of the application or affect its relative ranking, e.g., a missing certification, or missing signature).

To be considered for funding for FY 1991, an applicant must submit a Program Description, which must be received in the HUD Field Offices by 4 p.m. local time, August 26, 1991, which includes Standard Form 424 signed by its Chief Executive Officer or his or her designee and a narrative statement organized as follows:

1. *Program Activities.* A description of the applicant's proposed Rental Rehabilitation Program, consisting of (a) the activities the applicant proposes to undertake for the fiscal year, (b) *a description of why a Rental Rehabilitation Program is needed, and (c) a management plan for the operation of the program, which indicates the staff who will be working on the Rental Rehabilitation Program, their experience in rehabilitation, and the amount of their time that will be spent on the Rental Rehabilitation Program.*

2. *Neighborhood Selection.* The Program Description shall identify the neighborhood(s) in which assisted activities are to be carried out and provide information, for each neighborhood, to indicate compliance with the requirements of §§ 511.10 (c)(1) and (c)(2), including:

(a) A map indicating the boundaries of each neighborhood, or a description of the boundaries of each neighborhood;

(b) Median income of the neighborhood; and

(c) Current rent levels in the neighborhood; and a statement as to whether standard units are generally affordable to lower income families and the likelihood of their continued affordability for lower income families for the next five years.

Where the neighborhoods in which assisted activities are to be carried out are known at the time of submission of the Program Description, the applicant will indicate the evidence (such as recent market studies and analysis for the neighborhoods) upon which compliance with the requirements of section 511.10(c) is based. Where the neighborhoods are not known at that time, the applicant will indicate the type of neighborhood selection guidelines or other means it will use to ensure compliance with these requirements.

3. *Lower-Income Benefit.* A description of how the applicant intends to ensure that the applicable percentage of rental rehabilitation grant amounts will be used for the benefit of lower-income families, as specified in section 511.10(a). The description will indicate how the grantee plans to achieve the specified level of lower-income benefit.

4. *Use of Rental Rehabilitation Grants for Housing for Families.* A description of the applicant's plan to ensure that an equitable share of rental rehabilitation grant amounts will be used to assist in the provision of housing designed for occupancy by families with children, particularly families requiring three or more bedrooms. The applicant will describe how it plans to give priority to projects containing three or more bedroom

units. If applicable, the applicant will include an explanation of why it proposes to use less than 70 percent of its rental rehabilitation grant for the rehabilitation of units containing two or more bedrooms, as prescribed in section 511.10(b) (1) and (2). Such explanation shall include the citation of any local seismic standard ordinance.

5. *Selection of Proposals.* A statement of the procedures and standards that will govern the selection of proposals by the applicant. These procedures and standards must take into account:

a. The extent to which the proposal represents the efficient use of rental rehabilitation grant amounts;

b. The extent to which the proposal will minimize displacement of lower income tenants in accordance with the displacement and tenant assistance policy in § 511.14; and

c. The extent to which the dwelling units involved will be adequately maintained and operated with rents at the level proposed. This may consist of a description of plans for requiring a sufficient equity interest, risk, or other involvement in selected projects by private investors and lenders to ensure appropriate incentives to maintain and operate units after rehabilitation.

d. The extent to which priority is to be given to the selection of projects with units that are occupied by very low-income families before rehabilitation that do not meet the applicant's rehabilitation standards adopted pursuant to 24 CFR 511.10(e) and also to projects that will result in dwelling units that are to be made readily accessible to and usable by individuals with handicaps. (See 24 CFR 511.10(g)).

6. *Financial Feasibility.* Evidence demonstrating the financial feasibility of the proposed Rental Rehabilitation Program, including the availability of non-Federal governmental and private resources. Where the applicant has not identified specific projects at the time of submission of the Program Description, the evidence will consist of the applicant's plans to ensure its program's financial feasibility, including plans to obtain non-Federal resources.

7. *Neighborhood Preservation.* An estimate of the effect of the proposed Rental Rehabilitation Program on neighborhood preservation.

8. *Schedule for Committing Rental Rehabilitation Grant Amounts.* A quarterly schedule that demonstrates the applicant's plan to commit to specific local projects its rental rehabilitation grant for the fiscal year for which funding is sought. This schedule must at a minimum show that at least 50 percent of the total grant amount will be so committed within 9 months and 100 percent will be so committed within 12 months, after the date of HUD's execution of the grant agreement.

For this Program Description, the applicant should submit a schedule based on the amount of Rental Rehabilitation grant funds requested in Item 15 of this section. A revised schedule may be required if the applicant's program is approved for an amount different from the amount requested.

9. *Nondiscrimination and Equal Opportunity.* A statement of policy and procedures to be followed by the applicant to meet the requirements for affirmative marketing of units in rehabilitated projects as required in section 511.13(b).

This element must address each of the five (5) affirmative marketing procedures stated in section 511.13(b)(1) and describe how these affirmative marketing procedures will be achieved.

10. *Applicant's Organizational Structure.* The name, address, and telephone number of the agency and contact person responsible for administering the Rental Rehabilitation Program. *A description of the staff and dollar resources applicant will use to administer the program.*

11. *PHA Participation.* a. A Memorandum of Understanding (MOU) signed by the unit of general local government and the appropriate PHA in accordance with 24 CFR 511.40, if possible. If the PHA has not agreed to an MOU, the unit of general local government must include a statement describing its timetable for executing a MOU in accordance with 24 CFR 511.40 prior to commitment of grant amounts to specific projects, or, in the alternative, how it will meet the affordability and relocation requirements of the RRP without the use of section 8 resources.

b. If applicable, the name, address, and telephone number of the PHA contact person.

12. *High Cost.* If applicable, an explanation of why higher average per dwelling unit rental rehabilitation grant amounts for projects are proposed, as provided in section 511.11(e)(2)(ii).

13. *Amount of Rental Rehabilitation Grant Funds Requested. A statement by the applicant indicating the amount of rental rehabilitation grant funds requested for the fiscal year.*

14. *A Statement of The Applicant's Recent Past Rehabilitation Activities. This should include the number of units/properties rehabilitated, the source of funds, and the amount of public funds spent for the rehabilitation for each of the last 3 years. In addition, the applicant should briefly address each of the items listed under Factor 2 of the competitive selection factors in Section II–B below.*

5. *Certifications.* The applicant shall certify that:

a. The submission of the Program Description is authorized under State and local law (as applicable), and the applicant possesses the legal authority to carry out the Rental Rehabilitation Program described therein, in accordance with 24 CFR part 511;

b. Its Rental Rehabilitation Program was developed after consultation with the public and its Program Description has been made available to the public;

c. If applicable, its lower-income benefit standard should be reduced to 70 percent as provided by 24 CFR 511.10(a)(2); this certification will be accompanied by an explanation of the reasons why this reduced benefit standard is necessary, as provided in 24 CFR 511.10(a)(2).

d. It will comply with the acquisition and relocation requirements of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, as amended, implementing regulations at 49 CFR 24 part and the requirements of 24 CFR 511.14 which include adoption of a written tenant assistance policy.

e. It will conduct and administer its Rental Rehabilitation Program in accordance with the requirements of 24 CFR 511.

f. It will comply with the drug-free workplace requirements in accordance with 24 CFR part 24, subpart F.

g. If applicable, it will comply with the certification and disclosure requirements regarding lobbying at 24 CFR part 87. (Potential grantees should refer to 55 FR 6736 (February 26, 1990) or 24 CFR part 87 for the language for the certification and disclosure, which are contained in appendix A and appendix B to part 87, respectively.

Section II—The Selection System

A Program Description submitted for the HUD-Administered Rental Rehabilitation Program for Small Cities is evaluated in two stages. First, the HUD Field Office must determine the Program Description's acceptability under the criteria listed in section 511.21(a) of the Rental Rehabilitation Program regulations. Second, the Field Office must competitively rank the Program Descriptions pursuant to section 511.52(b) of the regulations and this RPS. Each Field Office shall apply a consistent approach to ranking all applications received in a particular fiscal year.

The following describes the two-stage review process for HUD-Administered Small Cities Program Descriptions:

A. Threshold Review

1. Was Program Description received within the time period established, including any extension that was granted by HUD?

2. Does Program Description contain evidence sufficient (on the basis of the Description or otherwise) to support each of its required elements?

—Does the Program Description address each of the required elements listed in section 511.20(b) and section I of this appendix?

—Is there sufficient information to support each required element?

—Are required certifications included (as required by section 511.20(c) of the Program Regulations and section I, Item 15 of this appendix)?

Note: If Program Description indicates that applicable percentage of lower-income benefit is 70 percent, appropriate certification should be included and the Program Description should contain the reasons necessary to support the reduction to 70 percent.

3. If applicable, has an acceptable Annual Performance Report (APR) for the preceding program year been received from the applicant? If not applicable, answer N.A.

4. Has the Housing Division advised that a participating Public Housing Agency's (PHA's) application for section 8 resources would be approvable, or in the alternative, has the community demonstrated that it can meet the affordability and relocation requirements of the RRP without section 8 resources?

If the answer to any of the above questions is no, the program description should not be approved.

B. Competitive Factors and Points

Factor 1. Need: (Data to be supplied by HUD)—200 points
a. Rental Households in Poverty
b. Poverty Rental Households in Pre-1940 Structures
c. Rental Households with One of Four Problems:
(1) High rent cost,
(2) Overcrowding,
(3) Incomplete kitchen facilities, or
(4) Incomplete plumbing

Factor 2. Past Performance in Housing and Community Development Activities—100 points
a. Rate of fund commitment for recent CDBG rehabilitation activities, if applicable: (20)
b. The promotion of fair housing and equal opportunity in its housing and community development activities: (20)
c. The quality of work accomplished through the CDBG rehabilitation activities: (20)
d. The lack of audit findings, serious monitoring findings, and/or litigation against the community for housing and community development activities: (20)
e. Extent to which past rehabilitation activities demonstrate a specific capacity to administer the Rental Rehabilitation Program: (20)

Factor 3. Program Administration—150 points
a. Quality of management plan and organizational structure: (100)
b. The readiness and ability of a PHA to administer vouchers and certificates in support of the locality's RRP or in the alternative a means of administering other resources to meet the affordability and relocation requirements: (50)

Factor 4. Quality and Impact of Proposed Program—150 points
a. The extent to which the description of the applicant's program activities indicates an understanding of the program goals: (20)
b. The likelihood that the applicant's selection of neighborhoods, or guidelines for selecting neighborhoods, will result in neighborhoods with rents affordable to lower-income families and neighborhoods where the median income is equal to or less than 80 percent of the median income for the area: (30)
c. Reasonableness of the applicant's description for achieving lower-income benefit: (20)
d. Extent to which applicant gives priority for rehabilitating units suitable for large families with children, particularly families requiring three or more bedrooms: (20)
e. Adequacy of description of how priority is to be given to the rehabilitation of units which are substandard and occupied by very low-income families and adequacy of description of how priority is to be given to the rehabilitation of units accessible to and usable by individuals with handicaps: (20)
f. Reasonableness of applicant's schedule for implementing its Rental Rehabilitation Program: (20)
g. Extent to which applicant's proposed procedures for affirmative marketing indicate an understanding of fair housing objectives; appear to be adequate for informing eligible persons about the rehabilitated housing regardless of race, color, religion, sex or national origin; and include a method for assessing the results of actions taken by the grantee, (recipient) and owner: (20)

Applicant's Score (Total of Factors 1, 2, 3 and 4 above) _____

Total Points Possible: 600

C. Evaluation of Competitive Factors

Based on the evaluation of competitive factors, an applicant will be given points from zero (0) to the maximum points possible for each factor, as indicated in the preceding section.

Factor 1—Need Factor

The Bureau of the Census supplies the data for the need factors which account for 200 points. These factors are the same that are used to allocate Rental Rehabilitation Program funds to localities receiving a direct formula allocation and reflect the need for assistance under the Rental Rehabilitation Program.

Factor 2—Past Performance Factor

The Field Office may give up to 100 points based on the applicant's past performance in community development and housing programs. The applicant's statement in response to Item 14 in the Program Description should be considered as well as the Field Office's knowledge of the applicant's past performance. In evaluating the applicant's performance, the following will be considered:

a. The rate of fund commitment for recent CDBG property rehabilitation activity: The extent to which the applicant's productivity in its rehabilitation program has been satisfactory and rehabilitation projects have been completed in a reasonable time.

b. The promotion of fair housing and equal opportunity: The extent to which the applicant has promoted fair housing and equal opportunity in its housing and community development programs. The reviewer will consider the applicant's performance with respect to nondiscrimination in providing benefits, affirmatively furthering fair housing, use of minority and women-owned businesses and employment of women and minorities. Staff will consider any recent monitoring and compliance review conclusions and any related court findings/consent decrees.

c. The quality of work accomplished through the locality's CDBG program: The extent to which good quality work has been performed. Field Office staff monitoring the locality's rehabilitation program have found quality work and also the lack of complaints from recipients of CDBG rehabilitation assistance.

d. The lack of (1) audit findings, (2) serious monitoring findings, and/or (3) litigation against the community for its housing and community development activities.

e. Extent to which past rehabilitation activities demonstrate a specific capacity to administer the Rental Rehabilitation Program: Field staff should consider whether the locality's past experience would help it to run a Rental Rehabilitation Program, such as previous experience in the Rental Rehabilitation Program. For localities that have participated previously in the Rental Rehabilitation Program:
—Whether market rents of 80 percent or more of the units rehabilitated in the program are affordable to lower-income families (at or below published section 8 FMRs or HUD-approved community-wide exception rents).
—Whether the program has met the statutory priority for providing housing for large families, (extent to which rental rehabilitation grant amounts are used to rehabilitate units containing two or more bedrooms and three or more bedrooms).
—Whether the program has met the priority of rehabilitating substandard units occupied by very low-income families and also for projects that will be made readily accessible to and useable by individuals with handicaps.
—Extent to which more than 80 percent of the units have market rents affordable to lower-income families.
—Extent to which gross amount of public funds (as determined by HUD) used for rehabilitation per unit have been minimized and the extent to which the amount of public subsidy funds as a percentage of rehabilitation costs have been minimized.
—Extent of grantee management efficiency, based upon such measures as average cost of administration per unit assisted, average project processing time, quality and timeliness of reports, and other measures indicating sound program management.
—Extent to which rental rehabilitation grant amounts have been committed to specific projects and projects have been completed.

Factor 3—Program Administration Factor

a. Quality of Management Plan and Organizational Structure

Does the locality's management plan indicate a sufficient commitment of staff time and expertise to run a successful Rental Rehabilitation Program? Does the locality's management plan identify specific staff, their qualifications and what their responsibilities will be in the program? What has been the experience of the staff in previous housing and/or community development programs? Is the organization likely to work? In assigning points to this component of the Program Administration Factor, the Field Office staff will rely not only on what is stated in the locality's management plan, but also on their knowledge of the locality's present administrative capacity to administer housing and community development programs.

A good indication of the locality's continuing capacity to administer a Rental Rehabilitation Program is the locality's satisfactory past participation in the Rental Rehabilitation Program.

The Field Office will award up to 100 points for this component of the Program Administration Factor.

b. Availability of a PHA to Administer Section 8, or Alternative

Has the PHA developed an MOU with a PHA or submitted a schedule concerning its plans to do so? In the latter case, is there a letter of commitment from the PHA? If a PHA is not available, has the applicant described how it will handle tenant assistance and relocation requirements and has it identified the resources it will use? If the applicant has demonstrated the ability to adequately assist tenants either through a PHA or by an acceptable alternative, it should be awarded 50 points. If the applicant's proposal in this regard is not completely satisfactory, the Field Office should award no or fewer points depending on how significantly deficient the applicant's proposal is on this factor.

If the applicant receives less than a combined total of 150 points for the Past Performance and Program Administration Factors, it is doubtful that the applicant has the capacity to run a successful Rental Rehabilitation Program.

Factor 4—Quality and Impact of Proposed Program Factor

The Field Office will review the Program Description from each applicant and give either all, some, or none of the points for each of the seven questions pertaining to the quality of the application. Each application should be judged individually and the points given should reflect how well each applicant responds to the application requirements. All applications, however, should be evaluated in a consistent manner.

Completing the Evaluation of Applications and Allocating Funds

After the points are given for the four factors, the Field Office will total the points for each applicant and rank the applicants from high to low. Those Program Descriptions which do not meet the threshold review criteria in Section II–A above will not be included in the ranking.

A score of 400 or more should generally be considered acceptable and should receive funding. If the total funds available are sufficient to fund all the top applications, or those receiving a score of 400 or more, they should all receive funding.

If there are sufficient funds available to approve all applications that receive at least 300 points, the Field Office may consider funding those applications. Field Offices should not fund an application that receives fewer than 300 points, except where extenuating circumstances warrant. However, before allocating funds to the approvable applicants, Field Offices should consider the reasonableness of each approvable applicant's request for Rental Rehabilitation grant funds relative to the needs of other approvable applicants. Field Offices may reduce the requested amount if it is determined unreasonable.

If the funds available to the State (or Field Office jurisdiction part of a State) are not sufficient to fund all approvable applications, the Field Office may cut back the funds in one of several ways, such as:

(1) Giving the best application or applications their total request if those requests are considered reasonable and reducing funds to those receiving fewer points.

(2) Reducing every approvable applicant's request proportionately down to a fixed threshold.

(3) Starting at the top of the list and providing funding to as many of the localities (provided their funding requests are reasonable) as the total funds available would allow.

(4) If two or more applicants receive the same number of points in the evaluation system, the Field Office will consider the needs for a Rental Rehabilitation Program as indicated by Factor 1. If funds are available to fund only one of the applicants, the one with the greater need will be funded.

Chapter 6 (HUD-Administered Programs) and section IV of exhibit 6–1 of the Rental Rehabilitation Program Handbook (7360.01) provide a further explanation of the competitive factors and how HUD will review otherwise approvable Program Descriptions received in response to this NOFA, except as modified by this NOFA. Persons interested in obtaining this explanation may contact the Community Planning and Development Division in the nearest HUD Field Office or the Rehabilitation Management Division of the HUD Central Office cited at the beginning of this NOFA.

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Part IV

Nuclear Regulatory Commission

10 CFR Parts 2 and 35

Quality Management Program and Misadministrations; Final Rule

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 2 and 35

RIN 3150-AC65

Quality Management Program and Misadministrations

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending regulations governing therapeutic administrations of byproduct material and certain uses of radioactive sodium iodide to require implementation of a quality management program to provide high confidence that the byproduct material or radiation from byproduct material will be administered as directed by an authorized user physician. The Commission believes this performance-based amendment will result in enhanced patient safety in a cost-effective manner while allowing the flexibility necessary to minimize intrusion into medical judgments. This amendment also modifies the notification, reporting, and recordkeeping requirements related to the quality management program and misadministrations.

EFFECTIVE DATE: January 27, 1992.

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I. Byproduct Material in Medicine

Use of Byproduct Material

Since 1946, growth in the medical applications of radioisotopes has been very rapid as their usefulness has become more apparent in diagnosis, therapy, and medical research. Current medical procedures employ a number of radioisotopes in a wide variety of chemical and physical forms. Nuclear medicine procedures for diagnostic and therapeutic applications involve the internal administration of radiolabeled tracers. Administration of the radiolabeled tracers, known as radiopharmaceuticals, may be performed by intravenous injection, inhalation, or oral ingestion. Diagnostic nuclear medicine in most cases involves imaging agents used for the delineation and localization of organ tissues by scintigraphy (e.g., technetium-99m hydroxymethylene diphosphonate used as a bone-seeking radiopharmaceutical). Organ function may be determined by quantifying the accumulation of radiopharmaceuticals in organs of interest (e.g., iodine-131 uptake studies used to assess thyroid function). Therapeutic nuclear medicine may use various radiopharmaceuticals for the treatment of disease by selective absorption or concentration (e.g., iodine-131 used to treat thyroid cancer). Other therapeutic applications may involve the use of radiopharmaceuticals in colloidal suspensions for the treatment of malignant tumors (e.g., phosphate-32 infusion for treatment of peritoneal or pleural effusions associated with malignant tumors).

Since the early 1900s, radiation therapy has become one of the major modalities of treatment in the management of neoplastic disease, generally referred to as cancer. Radiation therapy may also be used as a palliative agent in the medical treatment process. The objective of conventional radiation therapy using a teletherapy sealed source is to deliver a precisely measured dose of radiation to a defined tumor volume. This is usually accomplished by delivering a dose in daily increments over several weeks. External beam radiation therapy has evolved using innovative technology that has led to the development of the gamma stereotactic radiosurgery device used for treatment of precisely defined intracranial targets (e.g., brain tumors and arteriovenous malformations).

Brachytherapy uses a variety of smaller sealed sources for localized treatment of cancer. Typically the sealed sources are either inserted in a cavity (e.g., cesium-137 sources used for intracavitary treatment of cervical cancer) or implanted in tissue (e.g., iodine-125 seeds used for interstitial treatment of prostate cancer). Various remote afterloading devices have been developed for low, medium, and high dose rate brachytherapy treatments.

State and Federal Regulations

Byproduct material or radiation from byproduct material is regulated by either State or Federal laws. Twenty-eight states, known as Agreement States, have entered into an agreement with the NRC to regulate the use of byproduct material (as authorized by section 274 of the Atomic Energy Act). These States issue licenses and currently regulate about 4,000 institutions, e.g., hospitals, clinics, or physicians in private practice.

The NRC regulates the administration of byproduct material or radiation from byproduct material in 22 States, the District of Columbia, the Commonwealth of Puerto Rico, and various territories of the United States and has licensed 2,000 civilian and military hospitals and clinics.

II. NRC's Regulatory Program

NRC's Policy

In a policy statement published on February 9, 1979 (44 FR 8242), entitled "Regulation of the Medical Uses of Radioisotopes; Statement of General Policy," the NRC stated:

(1) The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.

(2) The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

(3) The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

The NRC has the authority to regulate the medical use of byproduct material or radiation from byproduct material to protect the health and safety of patients, but also recognizes that physicians have the primary responsibility for the protection of their patients. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions that are in the best interest of their patients.

NRC's Responsibilities

The NRC distinguishes between the unavoidable risks attendant in purposefully prescribed and properly

performed clinical procedures and the unacceptable risks of improper or careless use. The NRC is responsible, as part of its public health and safety charge, to establish and enforce regulations that protect the public from risks of improper procedures or careless use.

Misadministration Reports

The NRC has analyzed therapy misadministrations, abnormal occurrences, and diagnostic misadministrations in the therapy range over the period of November 1980 through December 1990 for the NRC licensees. The results of the analysis for events that occurred from November 1980 through December 1988 were summarized in the preamble to the proposed rule published January 16, 1990 (55 FR 1439). The events that occurred in 1989 and 1990 were similar to the events from the earlier years except that the number of therapy events in 1990 was approximately double the average number of therapy events for the previous years. Table 1 provides a brief description of the therapy misadministrations, abnormal occurrences, and diagnostic misadministrations involving iodine that occurred in 1989 and 1990. Although some of the events listed in the table may have caused direct harm to the patients, the overall significance of these events is that they indicate a breakdown in the licensee's program for ensuring that byproduct material or radiation is administered as directed by the authorized user. It has been assumed that a proportional number of such occurrences has also taken place in the Agreement States although the data base is not yet complete.

The causes of these misadministrations and/or abnormal occurrences may be characterized by insufficient supervision, deficient procedures or failure to follow procedures, inattention to detail, and inadequate training.

These factors are often significant in causing or contributing to misadministrations or abnormal occurrences. The purpose of this rulemaking is to address these factors by requiring each applicable part 35 licensee to establish and implement a quality management program. Thus, each licensee will be required to have and implement procedures to ensure that the byproduct material or radiation from byproduct material is administered as directed by the authorized user physician. Improved training of personnel who handle and administer byproduct material can also reduce mistakes. However, this rulemaking does not address training; the need for training initiatives will be considered by NRC in the future.

TABLE 1.—MISADMINISTRATIONS, ABNORMAL OCCURRENCES, AND OTHER EVENTS

Date	Licensee	ST	Description
	NRC LICENSEES—1989		
	Teletherapy		
01/23	Abbott Northwestern Hospital [1]	MN	Wrong Treatment Site: Adm 250 rads to wrong thigh due to improper marking.
03/09	Kennebec Valley Med Ctr [1]	ME	Wrong Patient: Adm 100 rads to brain.
03/27	Indiana Univ School of Medicine [1]	IN	Wrong Treatment Site: Adm 9 fractions of 300 rads each to the wrong hip due to marking.
07/24	Worcester City Hospital [1]	MA	Wrong Patient: Adm 250 rads to spine.
	Brachytherapy		
01/23	Yale New Haven Hospital	CT	Wrong Dose: Adm 1000 rads, Rx 500 rads, due to wrong decay factor.
01/31	St. Luke's Hospital	MO	Wrong Dose: 56% underdose due to wrong source strength.
09/19	Med Ctr of Delaware	DE	Wrong Dose: Adm 1731 rads, Rx 3091 rads.
10/25	Children's Hospital	MA	Wrong Dose: Adm 3952 rads, Rx 4534 rads.
11/30	Yale New Haven Hospital	CT	Wrong Radioisotope: Adm 500 rads, Rx 2500 rads.
	Nuclear Medicine—Exceeding Diagnostic Range		
03/14	New England Med Ctr [1]	MA	Wrong Radiopharmaceutical: Adm 5 mCi I-131, Rx 1 mCi I-123.
05/23	Abbott Northwestern Hospital [1]	MN	Wrong Radiopharmaceutical: Adm 3 mCi I-131, Rx 300 μCi I-123.
10/18	Mayo Foundation [1]	MN	Wrong Dosage: Adm 1 mCi I-131, Rx 100 μCi I-131.
11/30	Kuakini Medical Center [1]	HI	Wrong Patient: Adm 9 mCi I-131.
	Nuclear Medicine—Diagnostic Range or Involving Iodine		
02/09	Warminister Central Hospital	PA	Wrong Patient: Adm 175 μCi I-131 hippuran.
02/28	Milwaukee County Med Center	WI	Wrong Patient: Adm 50 μCi I-131 hippuran.
02/28	Washington Hospital Center	DC	Wrong Patient: Adm 155 μCi I-131 hippuran.
03/20	Christian Hospital	MO	Wrong Patient: Adm 17 μCi I-131 sodium iodide.
04/03	VA Medical Center	FL	Wrong Radiopharmaceutical: Adm 0.33 mCi I-131 hippuran, Rx 5.29 mCi Tc-99m MAA.
05/15	Hershey Medical Center	PA	Wrong Radiopharmaceutical: Adm 0.5 mCi I-131 MIBG, Rx 0.5 mCi I-131 NP-59.
07/89	Montefiore Hospital	PA	Wrong Dosage: Adm 24 μCi I-131, Rx 12 μCi I-131.
	NRC LICENSEES—1990		
	Teletherapy		
02/08	Cleveland Clinic [1]	OH	Wrong Dose: Adm 3 fractions of 278 rads each, Rx 2 fractions.
02/16	Washington Hospital Ctr [1]	DC	Wrong Patient: Adm 45 rads to lung.
02/19	Geisinger Medical Center	PA	Wrong Dose: Adm 4200 rads, Rx 3000 rads due to 4 additional fractions.
03/12	Muskogee Reg Med Ctr [1]	OK	Wrong Treatment Site: Adm 2160 rads.
03/16	Riverside Reg Med Ctr [1]	VA	Wrong Patient: Adm 296 rads to brain.
03/19	St. Mary's Med Ctr [1]	MI	Wrong Treatment Site: Adm 250 rads.
04/20	St. Luke's Hospital	OH	Wrong Dose: Adm 4619 rads, Rx 5304 rads.
05/07	Indiana Univ School of Medicine	IN	Wrong Dose: Adm 1800 rads, Rx 1350 rads due to misinterpreting the prescription.
08/22	St. Luke's Hospital [1]	OH	Wrong Treatment Site: Adm 178 rads.
09/14	Presbyterian Hospital	PA	Wrong Dose: Adm 5225 rads, Rx 4500 rads due to 4 additional fractions.

TABLE 1.—MISADMINISTRATIONS, ABNORMAL OCCURRENCES, AND OTHER EVENTS—Continued

Date	Licensee	ST	Description
	Brachytherapy		
01/17	Monongahela Valley Hospital [1]	PA	Failure to Detect Dislodged Source: One dislodged cesium-137 source irradiated the patient's leg.
02/02	Ball Memorial Hospital [1]	IN	Wrong Treatment Site: Adm 1500 rads, sealed source in wrong location.
02/07	University of Wisconsin [1]	WI	Wrong Dose: Adm 4120 rads, Rx 3240 rads due to wrong input to the computer.
03/15	University of Wisconsin [1]	WI	Wrong Treatment Site: Adm 400 rads due to wrong input to the computer.
03/16	John F. Kennedy Hospital [1]	NJ	Failure to Detect Dislodged Source: Source dislodged and the patient's face irradiated 1032 rads.
03/21	Parkview Mem Hospital	IN	Failure to Detect Dislodged Source: Applicator pulled out by the patient, the patient's legs irradiated 623 rads.
03/90–05/90	St. Mary Med Ctr, Gary and Hobart [1]	IN	Pattern of Wrong Doses: Entire brachytherapy operations were investigated and suspended.
08/29	Univ of Cincinnati [1]	OH	Wrong Treatment Site: Most seeds were implanted outside the prostate.
09/17	Cooper Medical Center	NJ	Wrong Dose: Adm 1464 rads, Rx 3000 rads due to wrong treatment plan.
	Nuclear Medicine—Exceeding Diagnostic Range		
04/17	St Francis Med Ctr	PA	Wrong Dosage: Adm 56 mCi I–131, Rx 50 μCi I–131.
05/14	Overlook Hospital [1]	NJ	Wrong Radiopharmaceutical: Adm 1.4 mCi I–131, Rx 300 μCi I–123.
06/04	Valley Hospital	NJ	Wrong Dosage: Adm 4.51 mCi Sr–89, Rx 3.54 mCi Sr–89.
06/04	Valley Hospital	NJ	Wrong Dosage: Adm 4.02 mCi Sr–89, Rx 2.87 mCi Sr–89.
06/05	Mercy Memorial Med Ctr [1]	MI	Wrong Dosage: Adm 4.3 mCi I–131, Rx 50 μCi I–131.
06/19	Tripler Army Medical Center [1]	HI	Unintended Dose to Nursing Infant: An infant received dose from mother's milk due to 4.89 mCi I–131 adm to mother; infant thyroid ablated.
07/10	North County Hospital	VT	Unintended Dose to Fetus: A pregnant patient adm 15 μCi I–131; failed to ask if pregnant.
07/10	St. Vincent Med Ctr	PA	Wrong Dosage: Adm 110.1 mCi I–131, Rx 100 mCi I–131.
07/19	Brigham and Women's Hospital	MA	Wrong Dosage: Adm 180 mCi Dy–165, Rx 270 mCi Dy–165.
07/27	North Detroit General Hospital [1]	MI	Fraudulent Studies: Old imaging films submitted for current patients resulting in excess doses for repeated studies.
08/01	Frankford Hospital	PA	Wrong Dosage: Adm 20 mCi I–131, Rx 14 mCi I–131.
09/22	West Shore Hospital [1]	MI	Wrong Dosage: Adm 175 mCi Tc–99m, Rx 8 mCi Tc–99m.
10/15	William Beaumont Hospital [1]	MI	Wrong Dosage: Adm 315 mCi I–131, Rx 175 mCi I–131.
11/26	VA Medical Center [1]	CA	Wrong Radiopharmaceutical: Adm 168 mCi Tc–99m, Rx 5 mCi In–111.
	Nuclear Medicine—Diagnostic Range or Involving Iodine		
02/01	VA Edward Hines Jr. Medical Center	IL	Wrong Radiopharmaceutical: Adm 0.716 mCi I–131 Hippuran, Rx 3.5 mCi Tl–201.
02/05	VA Medical Center	CA	Wrong Radiopharmaceutical: Adm 1 mCi I–131 Iodochole, Rx 1 mCi I–131 MIBG.
03/20	Cleveland Clinic	OH	Wrong Dosage: Adm 130 μCi I–131, Rx 100 μCi I–131.
03/30	Downriver X-ray and Nuclear Diagnostics	MI	Wrong Dosage: Adm 100 μCi I–131, Rx 18 μCi I–131.
03/90	Davis Mem Hospital	WV	Wrong Dosage: Patients received 50% less dosage of I–131 than prescribed.
04/30	Johnson Willis Hospital	VA	Wrong Patient: Adm 9 μCi I–131 sodium iodide.
05/04	Central Plains Clinic	SD	Wrong Radiopharmaceutical: Adm 0.01 mCi I–125 Albumin, Rx 25 mCi Tc–99m.
08/07	Copley Hospital [1]	VT	Wrong Dosage: Adm 112 μCi I–131, Rx 10 μCi I–131.
09/05	Mansfield Gen Hospital	OH	Wrong Radiopharmaceutical: Adm I–123, Rx I–131.
09/13	West Park Hospital	WY	Wrong Dosage: Adm 0.0068 mCi I–131, Rx 1 mCi I–131.
10/30	Dept of Vet Affairs Medical Center	FL	Wrong Patient: Adm 0.262 mCi I–131 Hippuran.
12/05	Jersey Shore Hospital	PA	Wrong Radiopharmaceutical: Adm I–125 HSA, Rx Tc–99m UGA.
12/12	Jersey Shore Hospital	PA	Wrong Radiopharmaceutical: Adm I–125 HSA, Rx Tc–99m UGA.

[1] Misadministrations designated as abnormal occurrences.

Voluntary Initiatives

The NRC is aware of voluntary initiatives to improve quality assurance (QA). Examples include "Patterns of Care," a study managed by the American College of Radiology (ACR), "Quality Assurance Program in Radiation Oncology," prepared by ACR, and "Physical Aspects of Quality Assurance in Radiation Therapy," prepared by the American Association of Physicists in Medicine (AAPM).

The NRC encourages voluntary initiatives by the industry to develop consensus standards and will consider endorsing these standards in its regulatory guidance at an appropriate time. However, because these voluntary standards may not be adopted by all licensees, voluntary programs alone are not sufficient to ensure that the byproduct material will be administered as directed by the authorized user. Consequently, the NRC has determined that there is a need for this final rule.

Earlier NRC Efforts

On October 2, 1987 (52 FR 36942), the NRC published a proposed rule that would have required its part 35 licensees to implement some specific basic QA practices to reduce the number of mistakes in the therapeutic administration of radiopharmaceuticals or radiation from byproduct material and the administration of radioactive iodine. Public comments received on the proposed rule indicated that, although these proposed QA practices might reduce the number of mistakes, the imposition of prescriptive requirements might not afford sufficient flexibility for all licensees. Public comments, including recommendations from the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI), suggested that a performance-based rule should be promulgated, rather than a prescriptive rule. The ACMUI also suggested that a pilot program would be useful to determine the licensees' ability to meet

a proposed rule, to assess its impact, and to determine how to minimize its impact without decreasing its effectiveness. Furthermore, the ACMUI stated that, under existing NRC regulations, the definition of the term "misadministration" is unclear and that the related reporting requirements are confusing.

Subsequently, the NRC decided to develop a performance-based rule and a regulatory guide and, as a part of the same rulemaking, to review the term "misadministration," its scope and related reporting requirements. In addition, the NRC also decided to conduct a pilot program.

III. Publication of the Proposed Rule and Discussion of Related NRC Activities

The Proposed Rule

The NRC published proposed amendments to 10 CFR part 35 in the **Federal Register** on January 16, 1990 (55 FR 1439) and provided a 90-day public comment period. The proposed rule contained amendments that would require part 35 licensees to establish and implement a basic QA program. It also contained proposed modifications to the definition of "misadministration" and the associated reporting and recordkeeping requirements.

To collect additional information about the proposed rule from NRC and Agreement State licensees, the NRC conducted a pilot program. Also, the NRC conducted public workshops with professional associations, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Agreement States, and met with the NRC's ACMUI to obtain additional comments on the proposed rule. These workshops were open to the public, and prior notice was given through **Federal Register** announcements. Brief discussions of these activities are presented below.

The Pilot Program

The pilot program was conducted to provide a real-world test of the proposed rule in licensee hospitals and clinics and to gain insights beyond those generally obtained from the public comment process. Three basic questions were of interest:

(1) Can licensees develop QA programs to meet the objectives of the proposed rule following a performance-based approach using the regulatory guide or any other guidance of their choice?

(2) If NRC reviewed a licensee's written QA program, would the NRC agree that the program meets the objectives of the proposed rule?

(3) If NRC visited a licensee's hospital or clinic, would the NRC agree that the implemented program meets the objectives of the proposed rule?

Also, after the licensees had tested the proposed rule, the NRC wanted to learn from licensees if they had problems with the proposed rule and their recommendations on how the rule should be revised in order to minimize its cost and clarify its objectives without decreasing its effectiveness.

Based on the principles of acceptance sampling, the plan was to invite a group of 72 volunteer licensees that represent the U.S. population of part 35 type licensees. The total was divided into 24 NRC and 48 Agreement State volunteers because there are approximately twice as many Agreement State licensees as there are NRC licensees. Groups were defined using the five NRC regions and the 28 Agreement States. The number of volunteers invited from each group was in proportion to the number of licensees in that group. Also, it was desirable to have the volunteers represent specific licensee characteristics within each group, as well as possible, considering the number of volunteers randomly selected from that group. The specific licensee characteristics were class of licensee (i.e., teletherapy, brachytherapy, radiopharmaceutical therapy, and diagnostic nuclear medicine), type of facility (i.e., private or nonprivate), size of facility (i.e., small—up to 250 beds, or large—over 250 beds), and facility location (i.e., urban within a U.S. Bureau of Census Standard Metropolitan Statistical Area, or rural—otherwise).

Letters inviting participation in the pilot program were sent to a total of 185 licensees. Seventy-six institutions volunteered (27 NRC and 49 Agreement State licensees).

Five one-day workshops were held, one in each NRC region, to explain the overall process of the pilot program and to discuss the proposed rule and draft regulatory guide. Following these workshops, the volunteers developed QA programs that conformed to § 35.35 or amended their existing QA programs to meet the objectives of proposed § 35.35. The volunteers also conducted any necessary training in preparation for their trial use of the § 35.35-type QA programs. During a 60-day period from mid-May to mid-July 1990, the volunteers used their § 35.35-type QA programs for their administrations of byproduct material or radiation from byproduct material.

To address the first two questions stated above, the NRC evaluated each volunteer's written § 35.35-type QA program to determine whether it met the proposed objectives. To address the third question stated above, the NRC visited the hospitals or clinics of 18 (12 NRC and 6 Agreement State) volunteers to determine whether their § 35.35-type QA programs, as implemented, met the proposed objectives. These site visits were conducted during the 60-day trial use period.

At the end of the pilot program, five two-day workshops were held, one in each NRC region except Region V, to learn about the volunteers' experiences in using their § 35.35-type QA programs and to discuss the volunteers' problems with and recommendations on how to revise the proposed rule and draft regulatory guide. Prior to these workshops, each volunteer was asked to complete a written questionnaire as an evaluation of the proposed rule and draft regulatory guide. There were 64 volunteers (23 NRC licensees and 41 Agreement State licensees) who actually participated in all aspects of the pilot program. The following is a summary of the lessons learned from the pilot program.

(1) Licensees can develop acceptable QA programs under a performance-based approach.

(2) The licensees' programs, as written, did meet most of the proposed § 35.35 objectives, even without benefit of an iterative process (e.g., questions and revisions) as occurs during licensing.

(3) The licensees' programs as actually implemented were found during the 18 site visits to be more complete than the written programs in meeting the proposed § 35.35 objectives. Some programs completely met the objectives.

(4) Most licensees already had an existing QA program because of JCAHO or a professional society; thus, neither the incremental work nor the cost involved to meet the proposed § 35.35 objectives were substantial.

(5) Proposed § 35.35 objective number 1 to "ensure that the medical use is indicated for the patient's medical condition" and objective number 4 to "ensure that the responsible individuals understand the directions provided by the authorized user" should be deleted, but the other six objectives should be retained.

(6) The word "errors" in § 35.35(a) should be replaced with a term to specifically describe what is to be prevented.

(7) To avoid confusion in the thousands of hospitals that are already accredited by JCAHO, the NRC should use a term other than "quality assurance."

(8) The term "written directive" should be used instead of "prescription" to avoid confusion with existing medical practices.

(9) The sentence structure should be simplified by stating multiple requirements or criteria in lists, i.e., (a), (b), and (c).

(10) A required "written referral" for diagnostic procedures would be unnecessarily costly.

(11) The patient should be redundantly identified.

(12) The "annual comprehensive audit" should be replaced with an annual program review based on a random sample of patient administrations.

(13) The reporting requirements of proposed §§ 35.33 and 35.34 should be simplified.

(14) The reporting threshold criteria of an organ dose of 2 rems and a whole body dose of 0.5 rem should be modified because these criteria are exceeded during most routine diagnostic procedures.

(15) The procedure should be retained that allows the licensee to handle "events," i.e., mistakes that exceed a relatively low threshold, within its institution without reporting to NRC; events exceeding a higher threshold should be reported to NRC (or the applicable Agreement State).

A NUREG/CR report summarizing the pilot program is under preparation and will be published in the near future.

Public Workshops

ACNP and SNM

The NRC conducted a public workshop with representatives of the American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM) in Rockville, Maryland, on July 23, 1990. The proposed QA rule was compared with the current JCAHO Standards and with a JCAHO-type QA program for one hospital to determine if equivalence existed. It was concluded that the proposed QA rule is comparable to the JCAHO Standards. The ACNP and SNM provided various questions, comments, and recommendations regarding the proposed rule. Most fundamentally, ACNP and SNM representatives questioned the need for the rule and whether additional NRC requirements would contribute to reducing the number of misadministrations. The major ACNP-SNM recommendations are:

(1) Withdraw the proposed QA rule.

(2) Endorse the JCAHO accreditation process and allow NRC licensees to comply with JCAHO requirements in lieu of the proposed QA rule for diagnostic nuclear medicine administrations.

AAPM, ACMP, ACR, AES, and ASTRO

On November 19 and December 15, 1990, the NRC conducted public workshops with representatives of the American Association of Physicists in Medicine (AAPM), American College of Medical Physics (ACMP), American College of Radiology (ACR), American Endocurietherapy Society (AES), and American Society for Therapeutic Radiology and Oncology (ASTRO) in Reston, Virginia. The proposed QA rule, definitions, reporting requirements, and regulatory guide were discussed on a line-by-line basis. Numerous suggestions were provided by the representatives of each professional association. Their major recommendations are:

(1) Do not use the title "Quality Assurance Program" to avoid confusion with the existing JCAHO programs.

(2) Do not use the term "misadministration."

(3) Use "calculated" administered dose for teletherapy and brachytherapy.

(4) Increase the range of tolerance between calculated administered dose and prescribed dose in teletherapy and brachytherapy.

(5) Use "written directive" instead of "prescription."

(6) Remove the word ensure from the beginning of each proposed objective.

(7) Do not use the word prevent because it sounds too absolute.

(8) Allow events (i.e., mistakes that exceed a relatively low threshold) to be handled within the institution.

The JCAHO

The staff conducted a public workshop with the JCAHO in Chicago, Illinois, on December 17, 1990. The common elements of the proposed QA rule and JCAHO requirements were discussed. The staff attempted to determine if the NRC regulation, licensing, and inspection processes are equivalent to the JCAHO standards, accreditation, and survey processes. Based on this workshop, the NRC staff concluded the following:

(1) The JCAHO standards are nearly equivalent to the diagnostic components of the proposed QA rule with only minor modifications required to achieve equivalence.

(2) The JCAHO does not perform a licensing review prior to a facility survey; therefore, no equivalence exists with the NRC licensing process. However, the JCAHO awards accreditation only after a facility survey.

(3) The JCAHO survey process is partially equivalent to the NRC inspection process with the significant difference being the amount of time spent in the specific departments; that is, in most cases the NRC spends considerably more time.

Overall, although the JCAHO accreditation applies to the entire hospital and the NRC license would only apply to the radiation therapy and nuclear medicine departments, the two processes have similar objectives.

The Agreement States

The NRC conducted public workshops with representatives of the Agreement States on March 14, 1990, December 18 and 19, 1990, and February 7 and 8, 1991. The workshops were held in Rockville, Maryland; Irving, Texas; and San Mateo, California, respectively. The following Agreement States were represented at one or more of the workshops: Alabama, Arkansas, California, Illinois, Louisiana, Maryland, New York, Rhode Island, Texas, Utah, and Washington. A representative from the City of New York also attended two workshops. The Agreement States that provided written comments that were incorporated into the record during the San Mateo, California, workshop were Alabama, Kentucky, Nebraska, North Dakota, Oregon, and Utah. The proposed QA rule (and subsequent draft revisions), definitions, reporting requirements, and regulatory guide were discussed. The Agreement States provided line-by-line recommendations. The major recommendations provided by the representatives are:

(1) All administrations of byproduct material or radiation from byproduct material should be approved by the authorized user prior to administration.

(2) Do not use the title "Basic Quality Assurance Program" to avoid confusion with the JCAHO program.

(3) Revise the proposed dose threshold levels for "events" and "misadministrations."

(4) The rule, definitions, and reporting requirements should be revised based on recommendations from the ACMUI on January 14 and 15, 1991, and should be republished for public comment.

(5) The proposed regulations should not be a matter of compatibility for Agreement States.

(6) If the proposed regulations are required to be adopted by the Agreement States, then compatibility requirements should be established at no higher than Division 3.

The ACMUI

The NRC staff presented a draft final rule, reporting requirements, and associated definitions to the ACMUI during a public meeting on January 14

and 15, 1991, in Alexandria, Virginia. The ACMUI is an advisory body, currently composed of physicians, medical physicists, a radiopharmacist, and a technologist, established for advising the NRC staff on matters involving the administration of byproduct material and radiation from byproduct material. The ACMUI devoted one and a half days to a line-by-line discussion of the draft final rule, reporting requirements, and associated definitions. The NRC staff also met with a Subcommittee of the ACMUI in a public workshop on March 26, 1991, in St. Louis, Missouri, to discuss the same topics. The major ACMUI recommendations on the draft final rule as of March 1991 are:

(1) Do not include diagnostic components and associated definitions in the final rule.

(2) Retain the therapy components and the use of a "written directive."

(3) Do not use the word "prevention" because it sounds too absolute.

(4) Do not include any assessment of the patient's pregnancy and nursing status in the objectives of the final rule.

(5) Use the term "reportable event" instead of "misadministration."

(6) Add a dose threshold criterion for reporting diagnostic events, such as the dose to the patient exceeds 5 rems effective dose equivalent.

(7) Do not include "unintended dosage to an embryo or fetus or to a nursing infant" as criteria for a reportable event.

(8) Change the time period for patient notification of a reportable event from 24 hours to 15 days to allow adequate time to calculate the actual dose delivered in complex situations.

(9) Retain the requirements for therapy events to be evaluated and responded to within the licensee's institution.

(10) Delete the requirement to notify the referring physician in the case of a reportable event.

(11) Allow the report to the patient to be a summary description of the event in language that the patient can understand rather than a copy of the technical report sent to the NRC.

(12) Allow the licensee to make modifications to maximize the program's efficiency and require a copy of the modifications to be provided to the NRC Regional Office within 30 days.

At its meeting on May 10, 1991, the ACMUI recommended that no quality management or quality assurance rule on medical use of any kind is needed or appropriate.

Public Comments and NRC Responses

About 3,000 copies of the notice of the proposed rulemaking as published in the Federal Register (January 16, 1990; 55 FR 1439) were mailed in January 1990 to all applicable licensees under 10 CFR part 35, Agreement State and Non-Agreement State agencies, professional associations, and other interested groups.

The NRC received 79 comment letters from many different sources in response to the proposed rule. In terms of the types of organizations, there were 52 comment letters from hospitals and clinics, 12 from professional associations, 6 from Agreement State or local government agencies (1 letter contained comments from 5 Agreement States), 3 from pharmacies, and 6 from individuals. In terms of professions, the tally is 32 from physicists or technologists, 26 from physicians, 8 from pharmacists, and 13 others. Forty-seven letters (60 percent) opposed the proposed rule. Twenty-eight letters (35 percent) did not specifically indicate support or opposition for the rule, but did suggest modifications. Four letters (5 percent) supported the rule.

General categories of public comments and NRC's responses are presented below. In Section IV entitled "Discussion of Final Rule Text," modifications of the proposed rule that are due, in part, to specific public comments are indicated. Some comment letters also addressed items in the draft regulatory guide. The comments on the regulatory guide will not be discussed here, but they were considered during the preparation of the final regulatory guide.

(1) Many commenters stated that the quality assurance rule represents an unwarranted intrusion into the practice of medicine. They stated that the NRC should concentrate its efforts on radiation protection.

Response. The NRC agrees that any intrusion into medical judgments affecting patients should be minimized. The purpose of the rule, however, is not to limit the authorized user, but to ensure that the licensee establishes procedures to control the administration of byproduct material or radiation from byproduct material. The rule concentrates on the question of whether each administration of byproduct material by the healthcare workers, upon whom the authorized user depends, is, in fact, administered as directed by the authorized user. The NRC recognizes that radiation therapy is a dynamic process and that the authorized user has the right and the responsibility to modify a previously written directive, prior to continuing treatment, depending upon the progress of the patient. The NRC believes that requiring a licensee to ensure that the process of administering byproduct material is conducted as directed by the authorized user is directly related to the radiation protection of the patient and does not constitute an unwarranted intrusion into medical judgments.

The Commission notes that similar comments were raised by members of the medical community on the Commission's original proposed misadministration reporting rule published for comment on July 7, 1978 (43 FR 29297). For the reasons stated in the notice that accompanied the final misadministration rule on May 14, 1980 (45 FR 31701), the Commission believed that these requirements were justified to identify the causes of misadministrations in order to correct them and prevent their recurrence. This view was consistent with the conclusions of a review performed by the General Accounting Office (EMD–79–16; January 1979), which stated:

> "In our view, requiring medical licensees to report misadministrations to NRC is not an intrusion into medical practice. This is clearly consistent with NRC regulatory responsibilities and a necessary part of an effective nuclear medicine regulatory program. Without this kind of feedback on incidents affecting the public health and safety, NRC cannot be sure it is adequately regulating the possession and use of nuclear materials in medical practice.

The Commission reaffirms these conclusions in promulgating the requirements in today's notice and notes that, contrary to the views expressed a decade ago on the potential impacts of the misadministration requirements, experience with these requirements to date has not shown the reporting and notification requirements to be a problem or an unreasonable burden on the regulated community.

(2) Some commenters stated that the proposed rule would have little effect on reducing the reported mistakes. Almost all commenters supported the goal of reducing mistakes and stated that most facilities already have good quality assurance programs. In fact, some commenters pointed out that the frequency of reported mistakes is already small and that the proposed rule could not substantially reduce that frequency.

Response. The NRC has analyzed the reported mistakes involving byproduct material since 1980. The results of the analyses suggest that the major causes are insufficient supervision, deficient procedures or failure to follow procedures, inadequate training, or inattention to details. Although the rate has been very low, the number of reported mistakes in therapeutic

administrations in 1990 was almost double the average number for previous years.

As stated in the NRC's Policy Statement on Medical Uses of Radioisotopes, the risk to the patient can be significant for mistakes involving all therapeutic and certain diagnostic procedures. Therefore, the licensees should make every effort to prevent mistakes in therapeutic administrations. The NRC believes that after a licensee implements the quality management (QM) program, most mistakes will be detected and corrected, thus minimizing the occurrence of misadministrations. (See comment 6 regarding the use of the term "quality management program," instead of "quality assurance program.") Therefore, to ensure adequate patient safety it is necessary for the NRC to require licensees to implement a QM program sufficient to ensure that the byproduct material or radiation from byproduct material is administered as directed by the authorized user.

The NRC realizes that it is impossible to prevent all mistakes, but believes that licensees should do their best to avoid them. The rule will emphasize the importance of a QM program and the need for each worker to participate in the program.

(3) Many commenters stated that the cost of implementing the proposed rule would be high with little potential for a corresponding reduction in mistakes. Thus, the commenters stated that the implementation of the proposed rule cannot be justified.

Response. In light of the public comments, lessons learned from the pilot program, and recommendations from the professional associations and the ACMUI, the proposed rule has been modified significantly to reduce cost without significantly reducing the level of protection. The proposed requirements that would have had minimal impact on risk have been eliminated to make the final rule more cost effective (e.g., deleting the diagnostic components of the proposed rule). Considering that several proposed provisions or actions have been eliminated, i.e., written diagnostic referrals, diagnostic events, specific investigations by the Radiation Safety Officer, and reports to licensee management on diagnostic events, as well as the adoption of other suggestions and the performance-based approach, the NRC believes that the cost effectiveness of the final rule has been optimized. Also, refer to the response to comment 2, above.

(4) Many commenters stated that the dose to patients from mistakes in diagnostic nuclear medicine administrations, except those procedures involving either sodium iodide I–125 or I–131, would not result in any measurable effect to the patient. They suggested that the requirements on the low-risk diagnostic procedures be eliminated.

Response. The NRC agrees with this comment and believes that the diagnostic use of radiopharmaceuticals is, in most cases, an area of relatively low radiation risk to patients. The ACMUI also advised the NRC that the diagnostic components should be eliminated from the final rule on the basis of cost versus benefit considerations. Thus, the QM portion of the final rule does not contain any diagnostic components for low risk radiopharmaceuticals. However, the final rule retains reporting requirements for deviations that exceed specific dose thresholds and requirements for higher risk radiopharmaceutical administrations, such as either sodium iodide I–125 or I–131 in quantities greater than 30 microcuries.

(5) Many commenters stated that the JCAHO and other professional associations, such as the ACR and the AAPM, are committed to quality assurance in medicine. They further stated that because these organizations have developed quality assurance programs to be used as voluntary standards and that many medical facilities are already using these programs, this rule is unnecessary. Also, commenters suggested that the NRC should consult with these organizations in the development of the rule and should permit the use of the voluntary standards in place of the rule to avoid duplicate efforts.

Response. Since the standards developed by professional associations are voluntary and since not all healthcare facilities are accredited by JCAHO, there is no guarantee that all licensee facilities will have a QM program. This rule is designed to ensure that each applicable licensee will implement a QM program. It is possible that the NRC may endorse one or more of the voluntary standards in regulatory guides in the future.

In response to the second suggestion, as discussed in Section III of this Supplementary Information, the NRC did meet with JCAHO and seven professional associations in 1990 and discussed ways to improve the proposed rule. Moreover, many of their suggestions were incorporated into the final rule.

In response to the third suggestion, since this is a performance-based rule, a licensee using a voluntary program may not need to replace its existing program, rather only supplement it, thereby ensuring that the objectives of the rule are being met. Thus, the use of a performance-based rule is intended to eliminate duplicate efforts. During the pilot program, the volunteers were asked about their existing QA programs and the amount of incremental work or cost required by the proposed rule. The volunteers responded that they were already meeting most of the objectives in the proposed rule as part of their existing QA programs. Thus, the incremental burden on most volunteers appears to be small, and that is expected to be the case in general for the typical licensee.

(6) Many commenters stated that the term "quality assurance" should not be used in this rule. Quality assurance, as used in all departments of a hospital, is a program to ensure that high quality medical care is provided to the patients. In a nuclear medicine or a radiation oncology department, quality assurance means responsiveness to perceived care needs, degree of symptom relief, degree to which the care is the technical state of the art, efficient use of funds available, appropriate use of health care resources, etc., as well as administering the byproduct material as directed by the authorized user. The commenters recommended that a different term be used in this rule to indicate that this rule addresses only the delivery process of administering byproduct material.

Response. The NRC agrees with this comment. The term "quality assurance" has the wrong connotation because under JCAHO it applies to the entire hospital. Since this rule addresses only the process of administering byproduct material, the term "quality management program" is used in the final rule to preserve the quality concept and avoid confusion with the existing "quality assurance" concept. The term quality management (QM) program will be used in subsequent discussions.

(7) Some commenters responded to the NRC's question, stated in the **Federal Register** notice, concerning the proper use of the term "misadministration," that it should be reserved for the most serious incidents such as overexposures resulting in death or serious injury. The commenters further stated that "misadministration" has a negative connotation that implies willful or gross negligence on the part of the physician and other hospital workers. Terms such as events, unscheduled events, incidents, or deviations were suggested as preferred replacements.

Response. The NRC disagrees with this comment. The term

"misadministration" correctly conveys that a mistake in the administration of byproduct material or radiation has occurred. It is neither pejorative, nor does it connote wrongdoing or malpractice, merely that byproduct material or radiation from byproduct material has, for whatever reason, not been administered as directed by the authorized user. Therefore, the term "misadministration" and its definition, modified as indicated in response to comments (8) and (9) below, have been retained.

(8) Some commenters stated that the proposed definitions of diagnostic misadministrations, therapy misadministrations, diagnostic events, and therapy events and the associated reporting requirements are overly complex and thus confusing. The commenters recommended that these definitions be simplified.

Response. The NRC agrees with this comment. Based on the lessons learned from the pilot program, suggestions made by the professional associations, the ACMUI, and the Agreement States, the terminology was simplified by (a) using only two terms, "recordable events" and "misadministration," and (b) moving the definition of all terms to § 35.2. (The terms recordable event and misadministration, as defined therein, will be used in subsequent discussions of this final amendment.)

(9) Many commenters stated that the proposed (and current) dose thresholds, i.e., an organ dose greater than 2 rems or a whole body dose greater than 0.5 rem, are too restrictive for determining whether to submit a report to the NRC. The commenters stated that at these dose levels, there are no biological effects to the patient. They further stated that many commonly used nuclear medicine diagnostic procedures routinely produce doses to nontarget organs in the range of two to eight rems. Clearly, these routine procedures should not constitute misadministrations.

Response. The NRC agrees that routine doses from diagnostic procedures represent a small amount of risk to the patient. Similar comments were made by professional societies and the ACMUI. Further, the ACMUI recommended a whole body threshold of 5 rems effective dose equivalent. Based on lessons learned from the pilot program, and the recommendations from public comments and the ACMUI, the organ threshold of 50 rems dose equivalent and a whole body threshold of 5 rems effective dose equivalent were adopted as thresholds for identifying misadministrations. These levels correspond to a threshold well below the onset of acute, clinically detectable adverse effects that may be caused by exposure to ionizing radiation (refer to NCRP Commentary No. 7, "Misadministration of Radioactive Byproduct Material—Scientific Background," National Council on Radiation Protection and Measurements, Bethesda, Maryland, July, 1991). Also, these levels correspond to the annual dose limits in the new 10 CFR part 20 for occupational workers which are thresholds for reporting overexposures to the NRC. Therefore, the Commission believes that applying these same thresholds to reporting of exposures to patients in excess of what was intended in diagnostic administrations is reasonable.

(10) Many commenters stated that the occurrence of a misadministration may not necessarily be an indication of an inadequate QM program. The commenters stated that, in fact, the identification of misadministrations could be viewed as evidence of a good QM program. Based on the "Patterns of Care Study," those hospitals with superior personnel and facilities had the highest cure rates. Why would one conclude that the hospitals with the lowest cure rates have adequate monitoring programs to detect misadministrations or have adequate QM programs? In particular, facilities that never report misadministrations may not have adequate QM programs for the detection of those misadministrations. Thus, it is not necessarily correct to associate good QM programs with no misadministrations or to associate inadequate QM programs with the occurrence of a misadministration. Furthermore, the commenters stated that the rule may discourage licensees from reporting misadministrations.

Response. The NRC agrees that the occurrence of a misadministration may not necessarily be evidence of inadequate QM. However, for example, either a case of gross negligence or a case of multiple misadministrations could be considered a lack of sufficient licensee management attention in implementing its QM program. With regard to reporting misadministrations, the Commission encourages licensees to promptly identify and report safety problems as reflected in the current enforcement policy. Furthermore, because the NRC wants to encourage and support licensee initiative for self-identification and correction of problems, the NRC may exercise enforcement discretion if certain conditions are met (refer to section G of appendix C, 10 CFR part 2).

(11) Some commenters questioned whether the NRC has enough qualified personnel to inspect QM programs in the licensees' hospitals, clinics, or private practice offices.

Response. In recent years, the NRC has increased its recruitment of personnel who have experience and knowledge either in nuclear medicine or in radiation therapy. Inspectors will be trained in all aspects of the rule and the regulatory guide and will be provided with specific inspection guidance. Accordingly, the NRC believes that it has enough qualified inspectors to conduct adequate inspections associated with this rule.

IV. Discussion of Final Rule Text

This section discusses the final rule text and the modifications made to the proposed rule. Throughout the following discussion, referring to the text of the final regulations may aid in understanding the specific points of this discussion.

Part 2—Rules of Practice for Domestic Licensing Proceedings

Appendix C. General Statement of Policy and Procedure for NRC Enforcement Actions

As stated in the proposed rule notice, the Commission views the occurrence of misadministrations as a subject of concern in the medical use of byproduct material and, in certain circumstances, may subject the licensee to enforcement action. Supplement VI of appendix C was modified by amending current examples dealing with misadministrations and adding specific examples of violations of the QM program. The examples added to part 2 of the final amendment are essentially the same as in Section V, "Enforcement," of the proposed amendment with the following modifications:

(1) At Severity Level III, the term "misadministration" is used to replace two proposed terms, "diagnostic misadministrations" and "therapy misadministrations."

(2) At Severity Level III, the example "failure to conduct adequate audits of a QM program or take prompt corrective actions for deficiencies identified through each audit" is moved to Severity Level IV. Also, the phrase "annual review" is used instead of the proposed word audit to conform to the rule language in the final amendment.

(3) At Severity Level IV, "failure to keep records" is added as an example.

Part 35—Medical Use of Byproduct Material

Section 35.2 Definitions

To consolidate the definitions, all definitions were moved to § 35.2. Based on the public comments, lessons learned from the pilot program, and recommendations from ACMUI, the following proposed definitions have been deleted from the final rule: Basic Quality Assurance, Diagnostic Event, and Diagnostic Referral. The other definitions were adopted with some modifications and are discussed in alphabetical order.

Diagnostic Clinical Procedures Manual. This definition has been modified as follows:

(1) The word "diagnostic" was added to clarify that this term only applies to diagnostic procedures.

(2) The proposed phrase "in a single binder" was deleted to permit the use of multiple binders.

Misadministration. The term "misadministration" as used in proposed § 35.2 and described in proposed §§ 35.33(b) and 35.34(b) has been retained. Table 2 provides a summary of the mistakes captured by the terms "misadministration" and "recordable event," although the requirements themselves should be consulted for the precise definitions of these terms.

TABLE 2.—MISTAKES CAPTURED BY THE TERMS "RECORDABLE EVENT" AND "MISADMINISTRATION"

Procedure	Recordable event	Misadministration
All Diagnostic Radiopharmaceuticals (including <30 μCi NaI, I-125 or I-131).		● Wrong patient, radiopharm, route, or dosage *and* ● Dose >5 rem Effective Dose Equivalent or 50 rem to organ.
Sodium Iodide Radiopharmaceuticals (where >30 μCi NaI I-125 or I-131).	● Admin dosage differs by >10% prescr dosage *and* >15 μCi. ● W/o written directive ● W/o daily dosage record	● Wrong patient ● Wrong radiopharm ● Admin dosage differs by >20% prescr dosage *and* >30 μCi.
Therapeutic Radiopharmaceuticals	● Admin dosage differs by >10% prescr dosage ● W/o written directive ● W/o daily dosage record	● Wrong patient ● Wrong radiopharm ● Wrong route of admin ● Admin dosage differs by >20% prescr dosage.
Teletherapy	● Calculated weekly dose 15% >prescr dose ● W/o written directive ● W/o daily dose record	● Wrong patient ● Wrong mode of treatment ● Wrong treatment site ● Calculated weekly dose 30% >prescr dose ● Calculated total dose differs by >20% total prescr dose ● If <3 fractions, calc total dose differs by >10% total prescr dose.
Brachytherapy	● Calc dose differs by >10% prescr dose ● W/o written directive ● W/o daily dose record	● Wrong patient ● Wrong radioisotope ● Wrong treatment site ● Leaking sources ● Failure to remove sources for a temporary implant ● Calculated admin dose differs by >20% prescr dose.
Gamma Stereotactic Radiosurgery	● W/o written directive ● W/o daily dose record	● Wrong patient ● Wrong treatment site ● Calculated total admin dose differs by >10% total prescr dose.

Six categories of misadministrations are defined in the final amendment. Paragraphs (2), (3), (4), (5) and a part of paragraph (1) replace therapy misadministration as proposed in § 35.34(b). Paragraph (6) and a part of paragraph (1) replace diagnostic misadministration as proposed in § 35.33(b).

Each category of misadministration under this definition is discussed here in the same sequence as it appears in the definition of misadministration in § 35.2 of the final rule.

(1) This paragraph applies to any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131. Paragraph (1)(i) is essentially the same as the corresponding items in proposed § 35.34(b)(1). However, the phrases "wrong target organ" and "wrong route of administration" were deleted because the thyroid is the only target organ for sodium iodide and it concentrates in the thyroid regardless of the route of administration. Paragraph (1)(ii) is the same as proposed § 35.34(b)(2) with two modifications. First, the threshold is now 20 percent, instead of 10 percent. Recall that if the administered dosage differs from the prescribed dosage by more than 10 percent, a recordable event has occurred that the licensee is required to respond to internally within the institution. Since the licensee is detecting these smaller deviations and taking the appropriate actions, these events do not need to be reported to NRC. However, larger deviations that exceed 20 percent are required to be reported because they could possibly indicate a deficiency in the QM program, not because they necessarily indicate a significant risk to the patient. For these reasons, the threshold was increased to 20 percent.

Secondly, an additional threshold of 30 microcuries is added. If the difference between the administered dosage and the prescribed dosage is 30 microcuries or less, it is not reported even if the difference exceeds 20 percent. This additional threshold was added to avoid the unnecessary work associated with the generation of reports on events with small differences and that pose relatively minor risks to the patients.

(2) This paragraph applies to any therapeutic radiopharmaceutical administration except those involving sodium iodide I–125 or I–131. Paragraph (2)(i) is the same as the corresponding items in proposed § 35.34(b)(1). The phrase "wrong target organ" was deleted because the

radiopharmaceutical (i.e., the correct chemical compound) and the route of administration determine the distribution of byproduct material among the organs or tissues, including the target organ. For example, a frequently used therapeutic radiopharmaceutical and route are sodium phosphate P–32 given intravenously, which is preferentially taken up by the target organ, the skeleton. The only way the wrong organ could be targeted is if the wrong radiopharmaceutical or route of administration were used. Both of these errors are already included in the definition of a misadministration. Thus, the wrong target organ is redundant.

Paragraph (2)(ii) is the same as proposed § 35.34(b)(2), with the exception that the threshold is now 20 percent for the same reasons discussed above, in category (1) of misadministration.

(3) This paragraph applies to gamma stereotactic radiosurgery and replaces a part of proposed § § 35.34(b)(1) and 35.34(b)(3). Paragraph (3)(i) is essentially the same as in proposed § 35.34(b)(1) with the exception that the phrase "wrong sealed source" was deleted because the device used for this type of procedure contains only cobalt-60 sources.

Paragraph (3)(ii) is the same as proposed § 35.34(b)(3)(i). The threshold of 10 percent for the total dose was retained because a large radiation dose is administered during the procedure, and therefore, deviations greater than 10 percent may have greater safety significance and need to be reported to NRC and promptly addressed by the licensee.

(4) This paragraph applies to teletherapy and it replaces proposed § 35.34(b)(3) and a part of § 35.34(b)(1). Paragraph (4)(i) is essentially the same as in proposed § 35.34(b)(1), but uses the phrase "wrong mode of treatment," rather than "wrong sealed source." This change is intended to clarify that teletherapy misadministrations capture the use of the wrong sealed source, as well as such events as a patient receiving cobalt-60 teletherapy when linear accelerator therapy was prescribed.

Paragraphs (4)(ii) through (4)(iv) replace proposed § 35.34(b)(3). The phrase "calculated administered dose" replaces the proposed phrase "administered dose" to clarify that a measured dose is not expected.

Paragraph (4)(ii) applies to teletherapy treatments with three or fewer fractions. It is the same as proposed § 35.34(b)(3)(i). The threshold of 10 percent for the total dose was retained because these procedures involve larger radiation doses per fraction than procedures with more than three fractions, and thus deviations greater than 10 percent may have greater safety significance. For example, a hemi-body teletherapy treatment might involve three fractional doses of 400 rads each fraction. One undesirable complication of a substantial overdose (e.g., 50 percent greater than the prescribed dose) for this treatment might be radiation pneumonitis or even death. Therefore, such events need to be promptly reported to the NRC and addressed by the licensee.

Paragraph (4)(iii) replaces proposed § 35.34(b)(3)(ii), with the exceptions of (a) the phrase "weekly dose" is used instead of "fractional dose" and (b) the phrase "30 percent greater than the weekly prescribed dose" is used instead of "greater than twice or less than one-half of the prescribed fractional dose." These changes allow a weekly comparison with the prescribed dose because many excellent therapy departments currently utilize a weekly chart check and the ACR recommends a weekly check. Recall that if the weekly administered dose exceeds the weekly prescribed dose by more than 15 percent, a recordable event has occurred, which the licensee will respond to internally to the institution. Since the licensee should be detecting the smaller weekly deviations and taking appropriate actions, calculated weekly administered doses that are 30 percent greater than the weekly prescribed doses will be reported because they could possibly indicate a deficiency in the QM program, which could be of greater safety significance, rather than because they necessarily indicate a risk to the patient. However, calculated weekly administered doses that are less than the weekly prescribed doses will not be reported because the criteria for the total doses capture significant deviations.

Paragraph (4)(iv) is the same as proposed § 35.34(b)(3)(i), with the exception that the threshold is now 20 percent. Since the licensee is monitoring weekly dose deviations and taking appropriate actions, a deviation from a total prescribed dose that exceeds 20 percent will be reported because it could possibly indicate a deficiency in the QM program, which could be of greater safety significance, rather than because it necessarily indicates a significant risk to the patient.

(5) This paragraph applies to brachytherapy and it replaces proposed § 35.34 (b)(4), (b)(5), and part of § 35.34(b)(1). Paragraph (5)(i) is the same as in proposed § 35.34(b)(1) with the following two modifications: (a) The phrase "wrong radioisotope" replaces the phrase "wrong sealed source" and (b) a parenthetical note for permanent implants was added to clarify the intent. "Radioisotope" is a more specific term than "sealed source." For permanent implants, the intent is to exclude from the determination of the wrong treatment site seeds that were implanted in the correct site but migrated outside that site.

Paragraphs (5)(ii) and (5)(iii) are essentially the same as proposed § 35.34(b)(4). The phrase "one or more sealed sources that are not removed upon completion of the procedure" was used in (5)(iii) instead of the proposed phrase "is lost or is unrecoverable during the brachytherapy treatment," to clarify the intent. The phrase "is lost or is unrecoverable" produced confusion among the pilot program volunteers, whereas, the phrase "is not removed upon completion" is clear and was recommended by the professional associations.

Paragraph (5)(iv) is the same as proposed § 35.34(b)(5) except that the phrase "calculated administered dose" was used instead of "administered dose" to clarify that a measured dose is not expected.

Note that, as specified in the definition of prescribed dose for brachytherapy, providing the total source strength and exposure time may be an alternative to providing the total dose. However, this alternative does not apply to high-dose-rate remote afterloading devices because the total dose must be specified prior to beginning the treatment.

(6) This paragraph applies to any diagnostic administration of a radiopharmaceutical other than sodium iodide I–125 or I–131, in quantities greater than 30 microcuries. This type of misadministration is similar to the diagnostic misadministrations in proposed § § 35.33(b) and 35.33(d). However, there are several differences:

(a) The phrase "wrong organ" in proposed § 35.33(b)(1) was deleted because the radiopharmaceutical (i.e., the correct chemical compound) and the route of administration determine the distribution of byproduct material among the organs or tissues, including the target organ as described previously for "recordable event."

(b) The thresholds for reporting in proposed § 35.33(d), "a whole body dose greater than 0.5 rem or an organ dose greater than 2 rems," were changed to "an effective dose equivalent of 5 rems or a dose equivalent of 50 rems to any individual organ" in the final

amendment. Both the public comments and the ACMUI recommendations suggested that the dose thresholds used for reporting should correspond to some kind of biological significance. These thresholds are well below the dose levels that would cause some harmful or detrimental deterministic effect as opposed to a stochastic effect. These thresholds correspond to the annual dose limits in the new 10 CFR part 20 for occupational workers, which are thresholds for reporting overexposure to the NRC.

(c) The phrase "if it involved the use of byproduct material not authorized for medical use in the license" in proposed § 35.33(d) was deleted because it is unnecessary. Under current regulations at 10 CFR 35.13, licensees are required to amend their licenses prior to using any byproduct material not authorized by their licenses; and at § 30.41(c), the licensee transferring the byproduct material must verify that the transferee is authorized by license to receive the type, form, and quantity of byproduct material to be transferred.

(d) The phrase "administration of a dosage differing by at least fivefold from the prescribed dosage" in proposed § 35.33(d) was replaced by dose thresholds for the same reasons as discussed in item (b) above.

Prescribed dosage. This definition has been modified as follows:

(1) The proposed phrase "before administration of the radiopharmaceutical" was deleted because it is part of the definition of "written directive;" thus, it is redundant.

(2) The proposed word "prescription" was replaced by "written directive." The reasons for the change are provided under the discussion of written directive.

(3) The proposed phrase "if the procedure is performed pursuant to a diagnostic referral" was deleted. A new phrase, "or in any appropriate record in accordance with the directions of authorized user for diagnostic procedures," was added to clarify that an authorized user may direct any diagnostic procedure that was not included in or departs from the diagnostic clinical procedures manual as long as the prescribed dosage is documented in an appropriate record.

Prescribed dose. This definition has been modified as follows:

(1) Gamma stereotactic radiosurgery was added to this definition. Although this type of procedure may be considered to be a single fraction teletherapy procedure, it is listed separately from teletherapy to allow for the differences between the two.

(2) The phrase "as documented in the written directive" was used to clarify where the actual prescribed dose is recorded.

(3) For brachytherapy, the phrase "the total source strength and exposure time" was used to specify an alternative way of defining the total dose. This phrase also calls attention to the importance of the exposure time. For temporary implants, after the sealed sources have been implanted and the appropriate calculations performed, administering the correct prescribed dose becomes a matter of removing the sealed sources on time (e.g., after 48 hours).

Recordable event. The term "recordable event" replaces "therapy event" as defined in proposed § 35.34(a). The term "recordable event" is used to indicate that a record and not a report is required. A recordable event is evaluated by the licensee pursuant to § 35.32(c) of the final amendment. The phrase "any therapeutic medical use not authorized by the license" in proposed § 35.34(a)(4) was deleted, because under current regulations at 10 CFR 35.13, the licensee is required to amend its license prior to using any byproduct material not authorized by its license; and at 10 CFR 30.41(c), the licensee transferring the byproduct material must verify that the transferee is authorized by license for the receipt of the type, form, and quantity of byproduct material to be transferred.

Each type of recordable event under this definition is discussed in the same sequence as it appears in the definition of recordable event in § 35.2 of the final rule:

(1) The phrase "written directive" was used to replace "prescription." Also, the phrase "a prior review of the patient's case by an authorized user or a physician under the supervision of an authorized user," in proposed § 35.34(a)(1), was deleted because if an authorized user signed the written directive, the phrase is not necessary.

(2) This type of recordable event, without daily recording, is essentially the same as published in the proposed rule with only minor editorial changes.

(3) This type of recordable event, in which dosage differs by more than 10 percent, applies to any administration of quantities greater than 30 microcuries of either sodium iodide I–125 or I–131. This recordable event is the same as in proposed § 35.34(b)(2) but with an additional threshold of 15 microcuries; i.e., if the difference between the administered dosage and the prescribed dosage is 15 microcuries or less, it is not a recordable event even if the difference exceeds 10 percent. This threshold was added to avoid unnecessary work because of the generation of recordable events caused by small differences (e.g., if the prescribed dosage is 35 microcuries, and the administered dosage is 40 microcuries, the difference exceeds 10 percent but does not exceed 15 microcuries; thus, it is not a recordable event).

(4) This type of recordable event, in which dosage differs by more than 10 percent, applies to radiopharmaceutical therapy, other than sodium iodide I–125 or I–131, and it is the same as in proposed § 35.34(b)(2). Thus, if the administered dosage differs from the prescribed dosage by more than 10 percent, it is a recordable event. If the difference exceeds 20 percent, it is handled as a misadministration.

(5) This type of recordable event, a wrong radiation dose, applies to teletherapy and is similar to the proposed § 35.34(a)(3) with the following modifications:

(a) The phrase "calculated weekly dose" was used to replace "fractional dose" to allow a weekly comparison with the prescribed dose because many therapy departments currently utilize a weekly chart check and the ACR recommends a weekly check;

(b) The word "calculated" was added to the weekly dose to clarify that a measured dose is not expected; and

(c) The dose threshold was decreased to 15 percent of the weekly prescribed dose instead of the proposed 20 percent of fractional dose to be less than the misadministration threshold for the total administered dose.

(6) This type of recordable event, also a wrong radiation dose, applies to brachytherapy and parallels item (5) above. If the calculated administered dose differs from the prescribed dose by more than 10 percent, it is a recordable event. If the difference exceeds 20 percent, it is handled as a misadministration. As previously discussed under the definition of prescribed dose for brachytherapy, the total source strength and exposure time may be used as an alternative to the total dose, except for the high-dose-rate remote afterloading devices. For a temporary implant of 48 hours, given that the total source strength has been implanted and is therefore a fixed value, a recordable event has occurred if the sealed sources are not removed within plus or minus 4.8 hours from 48 hours.

Written directive. This term replaces the word "prescription" as defined in proposed § 35.2. Based on the lessons learned from the pilot program and suggestions made by the professional associations, the Agreement States, the ACMUI, and the public comments, the

term "written directive" should be used to avoid any potential confusion with existing medical practices or the commonly used definition of prescription.

In the introductory paragraph, the proposed phrase "or a physician under the supervision of an authorized user" was deleted because such supervision is already allowed under the current § 35.25 entitled "Supervision." Thus, this phrase was redundant and unnecessary. Also in the same paragraph, the phrase "administration of byproduct material" replaces the phrase "medical use," and the phrase "prior to the administration of byproduct material or radiation from byproduct material except as specified in paragraph (6) of this definition" was added to clarify the intent that the written directive must be prepared prior to the administration of a radiopharmaceutical or radiation.

Paragraph (1) applies to any administration of quantities greater than 30 microcuries of either sodium iodide I–125 or I–131. This paragraph is essentially the same as paragraph (b) under the proposed definition of prescription, with the exception that the phrases "the radioisotope" and "physical form, chemical form, and route of administration" were deleted. These phrases are unnecessary because after specifying either sodium iodide I–125 or I–131, specifying the radioisotope and the chemical form would be redundant. The route of administration is not necessary because sodium iodide will always concentrate in the thyroid, regardless of the route.

Paragraph (2) applies to any therapeutic administration of a radiopharmaceutical, other than sodium iodide I–125 or I–131. This paragraph is essentially the same as paragraph (b) under the proposed definition of prescription, with the exception that it uses the phrase "the radiopharmaceutical" instead of the phrase "the radioisotope, physical form, and chemical form," because the word "radiopharmaceutical" includes the radioisotope and the chemical form. The physical form is not necessary because the route of administration must be specified.

Paragraph (3) applies to gamma stereotactic radiosurgery. This definition was separated from teletherapy in order to specify the unique types of information that need to be included in a written directive for this procedure.

Paragraph (4) applies to teletherapy procedures. This paragraph is the same as paragraph (c) in the proposed definition of prescription with the following modifications: (a) The phrase "dose per fraction" replaces the phrase "number of fractions" to emphasize the dose to be delivered in a single fraction and (b) the phrase "overall treatment period" was added to emphasize that the treatments will end after the specified number of weeks, unless the treatment period is revised by the authorized user prior to continuing.

Paragraph (5) applies to brachytherapy using high-dose-rate remote afterloading devices. This definition was separated from other brachytherapy procedures because of the need for the written directive to specify the total dose, along with other parameters, before administration of the radiation because the time period for exposure is very short when compared with other types of brachytherapy.

Paragraph (6) applies to brachytherapy procedures other than those specified in paragraph (5) above. This paragraph is essentially the same as paragraph (d) in the proposed definition of prescription. This paragraph requires the authorized user to specify, before implantation, the radioisotope, the source strengths, and the number of sources, but does not require the total dose because detailed calculations are required to determine the total dose after the sources are implanted. However, following implantation but before completion of the procedure, the authorized user must specify, among other parameters, the total source strength and exposure time. If the authorized user prefers, the total dose may be used instead of the total source strength and exposure time. This change, using total source strength and exposure time, provides an easy way of specifying the total dose and simplifies the determination of a misadministration. Since the total source strength is fixed when the sources are implanted, delivering the prescribed dose is a matter of using the correct (i.e., prescribed) exposure time. In other words, after implanting the correct sources, the exposure time (and total dose) will be correct if the sources are removed at the right time.

Section 35.8 Information Collection Requirements: OMB Approval

Paragraph (b) of this section was modified by adding § 35.32 to the list of sections that contain information collection requirements.

Section 35.25 Supervision

This section was not in the proposed rule. It is not necessary to publish this revision for public comment because the revisions are conformatory in nature. In the revised § 35.25(a)(1), the phrase "and in the licensee's written quality management program" was added to require each licensee to instruct the supervised individual in the procedures of the quality management program. Also in the revised § 35.25(a)(2), the phrase "follow the written radiation safety and quality management procedures established by the licensee" replaces the phrase "follow the procedures established by the Radiation Safety Officer" to clarify that the procedures in both the radiation safety programs and in the quality management program will be established by the licensee and must be followed by the supervised individual. Replacing the phrase "the Radiation Safety Officer" with the phrase "the licensee" is essentially no change since the Radiation Safety Officer is employed by the licensee and the licensee can delegate responsibilities.

Section 35.32 Quality Management Program

This section was renamed. NRC use of the term "quality assurance" led to some misunderstanding because under JCAHO's accreditation programs it applies to the entire hospital. Since this rule addresses only the delivery process of administering byproduct material or radiation from byproduct material, a new title, "Quality Management Program," is used in the final rule to preserve the quality concept and avoid any confusion or interference with the thousands of existing JCAHO quality assurance programs. Also, this section was designated as § 35.32 instead of the proposed designation § 35.35. This redesignation locates this section in front of § 35.33 and establishes a logical sequence. This section is very similar to the proposed § 35.35 with the following modifications.

In § 35.32(a), the phrase "to provide high confidence that the byproduct material or radiation from byproduct material will be administered as directed by the authorized user" replaces the proposed phrases "to prevent, detect, and correct the cause of errors in medical use" and "errors in medical use will be prevented." This modification states the objective of the QM program in a positive manner rather than a negative manner. Also, this modification was made in response to many public comments and workshop recommendations that the word "error" is too broad, and that the proposed language implies that all errors must be prevented. Also in the same paragraph, the phrase "as applicable" was added to clarify that this section is applicable only to those part 35 licensees who perform procedures for which a written directive is required.

The following proposed objectives were deleted in response to public comments and workshop recommendations:

(a) The proposed objective 1 "ensure that any medical use is indicated for the patient's medical condition" was deleted because it is not necessary. When directing the administration of byproduct material, it is already part of the authorized user's responsibility as a physician to ensure that the administration is indicated for the patient's medical condition. Further, the objectives of the QM program can nevertheless be achieved because the authorized user is required to sign a written directive prior to the administration.

(b) The proposed objective 3 became unnecessary after the diagnostic components of the QM program for most radiopharmaceuticals were deleted (as discussed previously).

(c) The proposed objective 4 was deleted because logically it would be unnecessary if the required condition of proposed objective 5 was met.

Public comments and workshop recommendations suggested that each objective should not start with the word "ensure" because trying to ensure that each objective is achieved has the same connotation as preventing all errors. In this manner, the word "ensure" produced unnecessary frustration. Thus, the word "ensure" was deleted from each objective in the final rule. Also, as discussed previously, the phrase "written directive" replaces the proposed word "prescription."

Each objective retained in the final rule is discussed below.

(1) Objective 1 is essentially the same as the proposed objective 2 except that: (a) The phrase "prior to each administration" replaces the proposed phrase "prior to any medical use" to clarify the intent to narrowly focus on the delivery to the patient of the byproduct material or radiation, (b) the different types of therapy procedures, including gamma stereotactic radiosurgery, were listed separately for ease of understanding, and (c) the phrase "sodium iodide" was added to exclude all other iodine compounds such as iodohippurate, which delivers a much smaller radiation dose to the thyroid as compared to an equal radiopharmaceutical dosage of sodium iodide.

Although many commenters questioned the need for requiring a written directive for diagnostic procedures involving quantities greater than 30 microcuries of either sodium iodide I–125 or I–131, the final rule retains this provision. The purpose of this provision is to put the authorized user in direct control of ordering and delivering a dosage greater than 30 microcuries of either sodium iodide I–125 or I–131. This dosage would deliver about 50 rems dose equivalent to the thyroid. However, in the reported mistakes of administration, there have been several cases of a technologist misinterpreting the referring physician's request, not checking with the authorized user, and administering millicurie amounts of sodium iodide I–131 instead of the requested microcurie amounts. Inadvertent administration of millicurie quantities of I–131 can cause significant adverse effects to the patient, such as ablating the thyroid gland or impairing its proper function. If the requirement for a written directive had been in effect at that time, a technologist could not administer a dosage greater than 30 microcuries of either sodium iodide I–125 or I–131 without a written directive dated and signed by the authorized user, and thus these events would probably have been prevented.

(2) Objective 2 is essentially the same as proposed objective 6 with the following modifications: (a) The phrase "by more than one method" was added to clarify the intent (e.g., ask the patient's name and also ask the patient for any one of the following: birth date, address, social security number and confirm this by comparing it with corresponding information in the patient's record; or check the name on the patient's ID bracelet; or ask for the patient's signature), (b) the proposed phrase "or the diagnostic referral" was deleted to conform with the removal of the diagnostic components.

(3) Objective 3 is essentially the same as the proposed objective 8 with the exception of using the phrase "final plans of treatment and related calculations" instead of the proposed phrase "treatment planning." The phrase "treatment planning" is not static and is often thought of as a continuing activity of the authorized user as the patient progresses. Also, the professional associations (e.g., ACR) stated that, initially, there may be several alternative plans of treatment, and following a discussion between the physicist or dosimetrist and the authorized user, a final plan of treatment would be selected and used. Thus, the change was necessary to avoid confusion as to which plan needed to be in accordance with the written directive. Also, gamma stereotactic radiosurgery was added to conform with similar changes, as discussed previously.

(4) Objective 4 is the same as the proposed objective 5 with the exception that the proposed phrase "or a diagnostic referral and clinical procedures manual" was deleted to conform with the removal of the diagnostic components.

(5) Objective 5 is essentially the same as the proposed objective 7 with the following modifications: (a) The phrase "and appropriate action is taken" was added to clarify the intent to have appropriate action taken after the unintended deviations are identified based on a recommendation from the pilot program participants and (b) the proposed phrase "or a diagnostic referral and clinical procedures manual" was deleted to conform to the removal of the diagnostic components.

Section 35.32(b) is essentially the same as proposed § 35.35(b) with the following modifications:

Section 35.32(b)(1) is the same as the first sentence of the proposed § 35.35(b)(1) except for the following changes: (a) The word "review" replaces the proposed phrase "comprehensive audit" to use a term more understandable to licensees based on lessons learned from the pilot programand (b) the phrase "including, since the last review, an evaluation of (i) a representative sample of patient administrations, (ii) all recordable events, and (iii) all misadministrations" was added to clarify the content of the review based on lessons learned from the pilot program.

Section 35.32(b)(2) is the same as the second sentence of the proposed § 35.35(b)(1) except for the following changes: (a) The word "licensee" replaces the proposed phrase "licensee's management" to simplify the final rule language, and (b) the phrase "if required, make modifications to meet the objectives of paragraph (a) of this section" replaces the proposed phrase "promptly implement modifications within 30 days that will prevent the recurrence of errors in medical use" to give the responsibility to the licensee for determining whether or when modifications are needed. This is in keeping with a performance-based approach.

Section 35.32(b)(3) is the same as the last sentence of proposed § 35.35(b)(1) with the exception of using the phrase "review, including the evaluations and findings of the review" instead of the proposed phrase "audit and management evaluation" to conform to the changes made in § 35.32 (b)(1) and (b)(2) and to use terms more understandable to licensees.

Section 35.32(c) replaces the proposed § 35.34(c) and a part of § 35.34(f)(2) pertaining to therapy events. Many

commenters and participants in the pilot program stated that the proposed recordkeeping and reporting requirements were too complicated and confusing. In the final rule, proposed requirements related to diagnostic events were eliminated following recommendations of the ACMUI, and the term "recordable event" replaces the proposed term "therapy event." If a recordable event occurs, the final rule allows the licensee to respond to that event within the institution, much like proposed § 35.34(a), but without requiring that a report be written to licensee management. The proposed requirements in §§ 35.34(c) and 35.34(f)(2) for therapy events were greatly simplified and consolidated in this paragraph to reduce the level of detail and avoid unnecessarily burdensome costs based on lessons learned from the pilot program.

The modifications are (a) the word "licensee" replaces the proposed phrases "Radiation Safety Officer" and "the licensee management" to provide flexibility for the licensee to determine the appropriate personnel to investigate the cause or take corrective action, (b) the phrase "assembling the relevant facts including the cause" replaced the proposed phrase "promptly investigate the cause" to reduce the emphasis on the speed of the investigation, and (c) the recordkeeping requirement was consolidated and simplified. The record retention period was shortened to three years; the proposed ten years is not necessary based on the current inspection frequency.

Many commenters asked about the meaning of the phrase "in an auditable form." The phrase means that the licensee must be able to produce a legible record, or copy of the record, within a reasonable period of time upon request by an NRC inspector. The records may be maintained in any location or by any means, including electronic or microfiche.

Section 35.32(d) is the same as § 35.34(f)(1) with the exception that two paragraphs are separated for clarity.

Section 35.32(e) is a simplified version of the proposed § 35.35(b)(2). In response to lessons learned from the pilot program and recommendations from the professional associations, the Agreement States, and the ACMUI, the final rule allows the licensee to modify its QM program to increase the efficiency of the program, i.e., the licensee may change its QM program provided the effectiveness of the QM program is not decreased. For example, suppose the licensee were conducting a monthly review of the QM program pursuant to § 35.32(b), but subsequently decided to review the QM program twice a year. Other changes are (a) the time period for submitting the program modifications to NRC was extended to 30 days from the proposed 15 days to allow more time to prepare the submission and (b) the proposed sentence related to NRC's prior approval of program modifications was deleted because this requirement is no longer necessary. Following the submittal of the program modifications, the NRC has the option of stopping the licensee from continuing to use the modified program if the NRC determines that the modifications would decrease the effectiveness of the program, or the option of obtaining more information, if required.

Section 35.32(f)(1) is the same as proposed § 35.35(c)(1) with the exception that the phrase "as applicable" was added to clarify that some Part 35 licensees will not be subject to this provision, i.e., those licensees administering byproduct material for which a written directive is not required.

Section 35.32(f)(2) is essentially the same as the proposed § 35.35(c)(2) with the following modifications: (a) The proposed phrase "designed in accordance with this section" was deleted because it is unnecessary, and (b) a new phrase, "along with a copy of the program," was added to require existing licensees to submit a copy of their program to the NRC on or before the effective date of the rule. Having a copy of the program will facilitate any inspections conducted prior to a license renewal date. The proposed § 35.35(c)(3) was unnecessary and was deleted because of the requirement to submit a copy of the QM program to the NRC.

Section 35.33 Notifications, Reports, and Records of Misadministrations

This section replaces the proposed § 35.33 (d) through (f) and § 35.34 (d) through (g). The final rule language was greatly simplified as compared to the proposed rule. The definitions of misadministration and recordable event were moved to § 35.2 and the two proposed sections §§ 35.33 and 35.34 were consolidated into a single section; thus, duplicative language was avoided.

Section 35.33(a) specifies the actions that a licensee must take when a misadministration is discovered and is essentially the same as the combination of the proposed § 35.33(d) and § 35.34(d) with certain modifications. The requirement to notify the referring physician was retained because the NRC expects that the authorized user and the referring physician would jointly decide whether and how to inform the patient.

For clarity, § 35.33(a) was divided into four parts. Each part is discussed below.

Section 35.33(a)(1) requires that the licensee notify the NRC by telephone. Two modifications were made to the proposed requirement. The phrase "the NRC Operations Center no later than the next calendar day" replaces the proposed phrase "the appropriate NRC Regional Office listed in Appendix D of 10 CFR Part 20 no later than the next Federal Government working day." During weekends or on holidays, the NRC Regional Offices are closed, but the NRC Operational Center remains open. Thus, by reporting to the NRC Operations Center, a licensee may make telephone notifications any calendar day and facilitate a timely and appropriate response from NRC.

Secondly, for misadministrations involving certain diagnostic dosages and radiopharmaceuticals, a notification requirement was added. The NRC believes that these occurrences warrant a telephone notification to the NRC because the definition of this type of misadministration requires that dose thresholds be exceeded, i.e., thresholds of 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ, as a result of one of four specific types of mistakes. The telephone notification will allow NRC to promptly take any necessary actions based on the circumstances, e.g., dispatch an inspector or consultant or notify other licensees of potential generic problems.

Section 35.33(a)(2) requires that the licensee submit a written report to the NRC. This requirement is the same as proposed with the exception that the phrase "and if the patient was informed, what information was provided to the patient" was added to complement the changes in § 35.33(a)(4) about furnishing a report in writing to the patient.

Section 35.33(a)(3) requires that the licensee notify the patient. This requirement is the same as the proposed requirement. Patients need to be promptly informed when a misadministration occurs so that they, in consultation with their personal physician, are allowed to make timely decisions regarding remedial and prospective health care. However, the licensee still has the responsibility to provide appropriate medical care to the patient, including any necessary remedial care as a result of the misadministration. To serve as a reminder for licensees, the phrase "including any necessary remedial care as a result of the misadministration" was added after the phrase "any

appropriate medical care" to the last sentence of § 35.33(a)(3).

Next-day notification of NRC was also retained because NRC needs to be informed promptly to take necessary actions. Examples of these actions include alerting other licensees or equipment manufacturers of a generic problem to prevent similar events, ensuring that the licensee takes corrective actions to prevent recurrence, and dispatching NRC inspectors or consultants, if warranted, to assess the facts surrounding the misadministration.

Section 35.33(a)(4) requires that the licensee furnish a written report to the patient if the patient was previously notified. This requirement is the same as proposed with the exception of allowing, as an alternative, a brief description of both the event and the consequences, as they may affect the patient, to be furnished to the patient.

Section 35.33(b) requires that the licensee keep records of each misadministration. This requirement is the same as § 35.34(f)(2) with the exception that the record retention period was reduced to 5 years from the proposed 10 years to reduce licensees' costs because a 5-year retention period is adequate for inspection purposes given that the current inspection frequency is less than 5 years.

Some commenters stated that there appeared to be an inconsistency between § 35.33(b) and § 35.33(a)(2). Section 35.33(a)(2) states that the report must not include the patient's name or other information that could lead to identification of the patient, but this paragraph states that the record must contain the patient's name. There is no inconsistency because the written report submitted to the NRC, as required by § 35.33(a)(2), could be released to the public if requested under the Freedom of Information Act. Thus, in order to protect the privacy of the patient, it would not be appropriate for this report to include the patient's name. On the other hand, the record required under § 35.33(b) is maintained at the licensee's facility, thus, the patient's name must be included since the relevant records are maintained according to the patient's name or identification number, e.g., social security number.

Section 35.33(c) is the same as proposed § 35.34(g) except for a minor editorial change.

V. Implementation Plan and Agreement State Compatibility

The effective date of this amendment will be January 27, 1992. On or before the effective date, each applicable part 35 licensee must implement the QM program and submit to the NRC a copy of the program and a written certification that the program has been implemented. After the effective date, each application for a new license or renewal under part 35, as applicable, will have to include a QM program as part of the application. The final guide, Regulatory Guide 8.33, "Quality Management Program," provides guidance on how to develop an acceptable QM program. On the effective date, part 35 licensees will be subject to the revised recordkeeping and reporting requirements of this amendment.

Because this amendment has safety significance for the Agreement State licensees as well as the NRC licensees, this final amendment is an item of compatibility for the Agreement States. All definitions contained in this rulemaking are Division 1 items of compatibility. The definitions contained in this rulemaking must be the same for all NRC and Agreement State licensees so that consistency will be maintained for the events reported quarterly to the Congress. Also, in order to have any meaningful analysis of the data from misadministrations, the criteria for what is to be reported needs to be consistent across all NRC and Agreement State licensees. Agreement States may require additional events to be recorded or reported (e.g., misadministrations involving accelerator-produced radioactive material that is not licensed by the NRC).

Additionally, the Commission believes that §§ 35.32 and 35.33 should be Division 2 items of compatibility because the QM programs required by the rule are necessary to ensure adequate protection of the public health and safety. The Agreement States regulate machine-produced radiation, naturally occurring and accelerator-produced radioactive material, as well as byproduct material; thus, the QM programs of their licensees need to be multi-purpose, of broader scope, and not limited to byproduct material considerations in order to cover the diagnostic and therapeutic modalities not regulated by the NRC (e.g., x-ray, and LINAC). Thus, the Agreement States will be allowed to establish QM requirements that are more stringent than NRC's requirements, but not less stringent. In accordance with existing NRC policy, the Commission expects the Agreement States to implement these new requirements by January 25, 1995. However, under the existing NRC Agreements, each Agreement State has the authority to implement the QM program by license conditions prior to establishing a regulation within the required 3-year period.

Although the Agreement States recommended that the revised final rule should be republished for public comment, this action is not necessary because the final rule is generally consistent with the scope of the proposed rule and does not pose any incremental burdens, and because the changes made to the rule are responsive to the extensive public comments and workshops that are part of the public record for this rulemaking. The proposed rule contained provisions for both diagnostic and therapeutic administrations of byproduct material or radiation from byproduct material. The scope of the final rule has been reduced by eliminating the provisions for most diagnostic administrations while retaining the other proposed provisions for therapeutic administrations and any administrations of quantities greater than 30 microcuries of either sodium iodide I–125 or I–131. Therefore, since in the proposed rule the public was given notice and an opportunity for comment on all the provisions that remain in the final rule, there is no need to republish those provisions.

VI. Administrative Statements

Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51, that this final amendment is not a major Federal action significantly affecting the quality of the human environment, and therefore an environmental impact statement is not required. The amendment requires each applicable NRC licensee to implement a quality management program to provide high confidence that the byproduct material or radiation from byproduct material will be administered as directed by the authorized user physician. This performance-based amendment will result in enhanced patient safety in a cost-effective manner while allowing the flexibility necessary to minimize intrusion into medical judgments. This amendment also modifies the notification, reporting, and recordkeeping requirements related to the QM program and misadministrations.

The implementation of a QM program will help ensure that the byproduct material will be administered as directed by the authorized user physician and, thus, will likely reduce unnecessary radiation exposures. It is expected that there will be no increase

in radiation exposure to the public or to the environment beyond the exposures currently resulting from delivering the byproduct material or radiation from byproduct material to the patient. The environmental assessment and finding of no significant impact on which this determination is based is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the environmental assessment and the finding of no significant impact are available from Dr. Tse (see **FOR FURTHER INFORMATION CONTACT** heading).

Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget approval number 3150–0010.

Public reporting burden for this collection of information is estimated to be 6,920 hours per year (for 3,300 applicable NRC and Agreement State licensees), or an average of about 2 hours per year per licensee, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Information and Reports Management Branch (MNBB–7714), U.S. Nuclear Regulatory Commission, Washington, DC 20555; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB–3019, (3150–0010), Office of Management and Budget, Washington, DC 20503.

Regulatory Analysis

The Commission has prepared a regulatory analysis for the final amendment. The analysis examines the benefits and impacts considered by the NRC. The regulatory analysis is available for inspection at the NRC Public Document Room at 2120 L Street NW. (Lower Level), Washington, DC. Single copies are available from Dr. Tse (see **FOR FURTHER INFORMATION CONTACT** heading).

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this amendment will not have a significant economic impact on a substantial number of small entities. The amendment affects about 1,100 NRC licensed institutions under 10 CFR part 35. Of these, about 150 are issued to physicians in private practice. Under the size standards adopted by the NRC (50 FR 50241; December 9, 1985), some of these licensees could be considered "small entities" for purposes of the Regulatory Flexibility Act (average gross annual receipts do not exceed $3.5 million for an institution and do not exceed $1 million for a private practice physician). The number of licensees that would fall into the small entity category is estimated to be a very small percentage of the total number of licensees and does not constitute a substantial number for purposes of the Regulatory Flexibility Act.

The amendment requires each applicable NRC licensee to implement a QM program to provide high confidence that the byproduct material or radiation from byproduct material will be administered as directed by the authorized user physician. This performance-based amendment will result in enhanced patient safety in a cost-effective manner while allowing the flexibility necessary to minimize intrusion into medical judgments. This amendment also modifies the notification, reporting, and recordkeeping requirements related to the QM program and misadministrations.

The Commission believes that most licensees currently have a QA program based on voluntary standards established by JCAHO and professional associations. Since this amendment is a performance-based rule, a licensee using a voluntary program may not need to replace its existing program, rather only supplement it, thereby ensuring that the objectives of the rule are being met. Furthermore, all licensees under 10 CFR part 35 or similar Agreement State regulations are currently subject to the existing reporting and recordkeeping requirements which, except for certain clarifications, are not significantly different from the reporting and recordkeeping requirements in the final amendment. Therefore, there should not be a significant economic impact on these small entities. (See the Regulatory Analysis for the anticipated economic impact of this regulation on licensees.)

Backfit Analysis

The NRC has determined that the backfit analysis is not required for this final amendment, because the backfit rule, 10 CFR 50.109, applies only to new requirements for power reactors (50 FR 38097, September 20, 1985). However, as noted above, the NRC has prepared a regulatory analysis examining the benefits and impacts of the final amendment.

List of Subjects

10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalty, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 35

Byproduct material, Criminal penalty, Drugs, Health facilities, Health professions, Incorporation by reference, Medical devices, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements.

Text of Final Regulations

Under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1954, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 2 and 35.

PART 2—RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

1. The authority citation for part 2 continues to read as follows:

Authority: Secs. 161, 181, 68 Stat. 948, 953, as amended (42 U.S.C. 2201, 2231); sec. 191, as amended, Pub. L. 87–615, 76 Stat. 409 (42 U.S.C. 2241); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); 5 U.S.C. 552.

Section 2.101 also issued under secs. 53, 62, 63, 81, 103, 104, 105, 68 Stat. 930, 932, 933, 935, 936, 937, 938, as amended (42 U.S.C. 2073, 2092, 2093, 2111, 2133, 2134, 2135); sec. 114(f), Pub. L. 97–425, 96 Stat. 2213, as amended (42 U.S.C. 10134(f)); sec. 102, Pub. L. 91–190, 83 Stat. 853, as amended (42 U.S.C. 4332); sec. 301, 88 Stat. 1248 (42 U.S.C. 5871). Sections 2.102, 2.103, 2.104, 2.105, 2.721 also issued under secs. 102, 103, 104, 105, 183, 189, 68 Stat. 936, 937, 938, 954, 955, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2233, 2239). Section 2.105 also issued under Pub. L. 97–415, 96 Stat. 2073 (42 U.S.C. 2239). Sections 2.200–2.206 also issued under secs. 186, 234, 68 Stat. 955, 83 Stat. 444, as amended (42 U.S.C. 2236, 2282); sec. 206, 88 Stat. 1246 (42 U.S.C. 5846). Sections 2.600–2.606 also issued under sec. 102, Pub. L. 91–190, 83 Stat. 853, as amended (42 U.S.C. 4332). Sections 2.700a, 2.719 also issued under 5 U.S.C. 554. Sections 2.754, 2.760, 2.770, 2.780 also issued under 5 U.S.C. 557. Section 2.764 and Table 1A of Appendix C also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 2.790 also issued under sec. 103, 68 Stat. 936, as amended (42 U.S.C. 2133) and 5 U.S.C. 552. Sections 2.800 and 2.808 also issued under 5 U.S.C. 553. Section 2.809 also issued under 5 U.S.C. 553 and sec. 29, Pub L.

85–256, 71 Stat. 579, as amended (42 U.S.C. 2039). Subpart K also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97–425, 96 Stat. 2230 (42 U.S.C. 10154). Subpart L also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239). Appendix A also issued under sec. 6, Pub. L. 91–560, 84 Stat. 1473 (42 U.S.C. 2135). Appendix B also issued under sec. 10, Pub. L. 99–240, 99 Stat. 1842 (42 U.S.C. 2021b et seq.).

2. In appendix C to part 2, supplement VI, paragraph C.7. is removed; paragraph C.8. is redesignated as C.7.; paragraphs A.4., B.3. and D.4. are added; and paragraphs C.6. and D.3 are revised to read as follows:

Appendix C to Part 2—General Statement of Policy and Procedure for NRC Enforcement Actions

* * * * *

Supplement VI—Severity Categories

Fuel Cycle and Materials Operations

A. * * *

4. Failure to follow the procedures of the quality management program, required by § 35.32, that results in a death or serious injury (e.g., substantial organ impairment) to a patient.

B. * * *

3. Failure to follow the procedures of the quality management program, required by § 35.32, that results in substantial overexposure (e.g., 50 percent greater than the prescribed dose) to a patient.

C. * * *

6. Substantial failure to implement the quality management program as required by § 35.32; failure to follow the procedures of the quality management program that results in a misadministration; or failure to report a misadministration.

D. * * *

3. Failure to follow the procedures of the quality management program, or failure to conduct the annual review or failure to take corrective actions as required by § 35.32; or

4. Failure to keep the records required by §§ 35.32 or 35.33.

* * * * *

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

3. The authority citation for part 35 is revised to read as follows:

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 35.11, 35.13, 35.20 (a) and (b), 35.21 (a) and (b), 35.22, 35.23, 35.25, 35.27 (a), (c) and (d), 35.31(a), 35.32(a), 35.49, 35.50 (a)–(d), 35.51 (a)–(c), 35.53 (a)–(b), 35.59 (a)–(c), (e)(1), (g) and (h), 35.60, 35.61, 35.70 (a)–(f), 35.75, 35.80 (a)–(e), 35.90, 35.92(a), 35.120, 35.200 (b) and (c), 35.204 (a) and (b), 35.205, 35.220, 35.300, 35.310(a), 35.315, 35.320, 35.400, 35.404(a), 35.406 (a) and (c), 35.410(a), 35.415, 35.420, 35.500, 35.520, 35.605, 35.606, 35.610 (a) and (b), 35.615, 35.620, 35.630 (a) and (b), 35.632 (a)–(f), 35.634 (a)–(e), 35.636 (a) and (b), 35.641 (a) and (b), 35.643 (a) and (b), 35.645 (a) and (b), 35.900, 35.910, 35.920, 35.930, 35.932, 35.934, 35.940, 35.941, 35.950, 35.960, 35.961, 35.970, and 35.971 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 35.14, 35.21(b), 35.22(b), 35.23(b), 35.27 (a) and (c), 35.29(b), 35.32 (b)–(f), 35.33 (a)–(b), 35.36(b) 35.50(e), 35.51(d), 35.53(c), 35.59 (d) and (e)(2), 35.59 (g) and (i), 35.70(g), 35.80(f), 35.92(b), 35.200(c), 35.204(c), 35.300(b), 35.310(b), 35.315(b), 35.404(b), 35.406 (b) and (d), 35.410(b), 35.415(b), 35.610(c), 35.615(d)(4), 35.630(c), 35.632(g), 35.634(f), 35.636(c), 35.641(c), 35.643(c), 35.645, and 35.647(c) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

4. In Subpart A—General Information, § 35.2, the term misadministration is revised; and the terms diagnostic clinical procedures manual, prescribed dosage, prescribed dose, recordable event, and written directive are added in alphabetical order:

§ 35.2 Definitions.

* * * * *

Diagnostic clinical procedures manual means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

* * * * *

Misadministration means the administration of:

(1) A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I–125 or I–131:

(i) Involving the wrong patient or wrong radiopharmaceutical, or

(ii) When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 30 microcuries.

(2) A therapeutic radiopharmaceutical dosage, other than sodium iodide I–125 or I–131:

(i) Involving the wrong patient, wrong radiopharmaceutical, or wrong route of administration; or

(ii) When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.

(3) A gamma stereotactic radiosurgery radiation dose:

(i) Involving the wrong patient or wrong treatment site; or

(ii) When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose.

(4) A teletherapy radiation dose:

(i) Involving the wrong patient, wrong mode of treatment, or wrong treatment site;

(ii) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;

(iii) When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or

(iv) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

(5) A brachytherapy radiation dose:

(i) Involving the wrong patient, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);

(ii) Involving a sealed source that is leaking;

(iii) When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or

(iv) When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.

(6) A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of either sodium iodide I–125 or I–131, both:

(i) Involving the wrong patient, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and

(ii) When the dose to the patient exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ.

* * * * *

Prescribed dosage means the quantity of radiopharmaceutical activity as documented:

(1) In a written directive; or

(2) Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

Prescribed dose means

(1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(2) For teletherapy, the total dose and dose per fraction as documented in the written directive; or

(3) For brachytherapy, either the total source strength and exposure time or the

total dose, as documented in the written directive.

* * * * *

Recordable event means the administration of:

(1) A radiopharmaceutical or radiation without a written directive where a written directive is required;

(2) A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;

(3) A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I–125 or I–131 when both:

(i) The administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage, and

(ii) The difference between the administered dosage and prescribed dosage exceeds 15 microcuries;

(4) A therapeutic radiopharmaceutical dosage, other than sodium iodide I–125 or I–131, when the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage;

(5) A teletherapy radiation dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose; or

(6) A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.

* * * * *

Written directive means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in paragraph (6) of this definition, containing the following information:

(1) For any administration of quantities greater than 30 microcuries of either sodium iodide I–125 or 1–131: the dosage;

(2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I–125 or I–131: the radiopharmaceutical, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;

(4) For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;

(5) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or

(6) For all other brachytherapy:

(i) Prior to implantation: the radioisotope, number of sources, and source strengths; and

(ii) After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

5. In Subpart A—General Information, § 35.8, paragraph (b) is revised to read as follows:

§ 35.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 35.12, 35.13, 35.14, 35.21, 35.22, 35.23, 35.27, 35.29, 35.31, 35.32, 35.33, 35.50, 35.51, 35.53, 35.59, 35.60, 35.61, 35.70, 35.80, 35.92, 35.204, 35.205, 35.310, 35.315, 35.404, 35.406, 35.410, 35.415, 35.606, 35.610, 35.615, 35.630, 35.632, 35.634, 35.636, 35.641, 35.643, 35.645, and 35.647.

* * * * *

6. In Subpart B—General Administrative Requirements, § 35.25, paragraphs (a)(1) and (a)(2) are revised to read as follows:

§ 35.25 Supervision.

(a) * * *

(1) Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of byproduct material and in the licensee's written quality management program;

(2) Require the supervised individual to follow the instructions of the supervising authorized user, follow the written radiation safety and quality management procedures established by the licensee, and comply with the regulations of this chapter and the license conditions with respect to the use of byproduct material; and

* * * * *

7. In Subpart B—General Administrative Requirements, § 35.32 is added to read as follows:

§ 35.32 Quality management program.

(a) Each applicant or licensee under this part, as applicable, shall establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following specific objectives:

(1) That, prior to administration, a written directive [1] is prepared for:

(i) Any teletherapy radiation dose;

(ii) Any gamma stereotactic radiosurgery radiation dose;

(iii) Any brachytherapy radiation dose;

(iv) Any administration of quantities greater than 30 microcuries of either sodium iodide I–125 or I–131; or

(v) Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I–125 or I–131;

(2) That, prior to each administration, the patient's identity is verified by more than one method as the individual named in the written directive;

(3) That final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

(4) That each administration is in accordance with the written directive; and

(5) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

(b) The licensee shall:

(1) Develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of:

(i) A representative sample of patient administrations,

(ii) All recordable events, and

(iii) All misadministrations

to verify compliance with all aspects of the quality management program; these reviews shall be conducted at intervals no greater than 12 months;

(2) Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the objectives of paragraph (a) of this section; and

(3) Retain records of each review, including the evaluations and findings of

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[1] If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

the review, in an auditable form for three years.

(c) The licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:

(1) Assembling the relevant facts including the cause;

(2) Identifying what, if any, corrective action is required to prevent recurrence; and

(3) Retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken.

(d) The licensee shall retain:

(1) Each written directive; and

(2) A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in paragraph (a)(1) above, in an auditable form, for three years after the date of administration.

(e) The licensee may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased. The licensee shall furnish the modification to the appropriate NRC Regional Office within 30 days after the modification has been made.

(f)(1) Each applicant for a new license, as applicable, shall submit to the appropriate NRC Regional Office in accordance with 10 CFR 30.6 a quality management program as part of the application for a license and implement the program upon issuance of the license by the NRC.

(2) Each existing licensee, as applicable, shall submit to the appropriate NRC Regional Office in accordance with 10 CFR 30.6 by January 27, 1992 a written certification that the quality management program has been implemented along with a copy of the program.

8. In Subpart B—General Administrative Requirements, § 35.33 is revised to read as follows:

§ 35.33 Notifications, reports, and records of misadministrations.

(a) For a misadministration:

(1) The licensee shall notify by telephone the NRC Operations Center [2] no later than the next calendar day after discovery of the misadministration.

(2) The licensee shall submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the misadministration. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the patient, or the patient's responsible relative or guardian (this person will be subsequently referred to as "the patient" in this section), and if not, why not, and if the patient was notified, what information was provided to the patient. The report must not include the patient's name or other information that could lead to identification of the patient.

(3) The licensee shall notify the referring physician and also notify the patient of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the patient or that, based on medical judgment, telling the patient would be harmful. The licensee is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within 24 hours, the licensee shall notify the patient as soon as possible thereafter. The licensee may not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

(4) If the patient was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either:

(i) A copy of the report that was submitted to the NRC; or

(ii) A brief description of both the event and the consequences as they may affect the patient, provided a statement is included that the report submitted to the NRC can be obtained from the licensee.

(b) Each licensee shall retain a record of each misadministration for five years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

(c) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, patients, or the patient's responsible relatives or guardians.

Dated at Rockville, Maryland, this 3rd day of July 1991.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

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[2] The commercial telephone number of the NRC Operations Center is (301) 951-0550.